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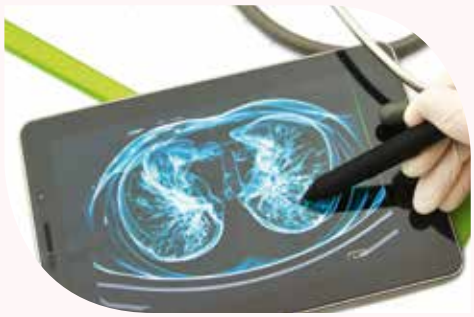

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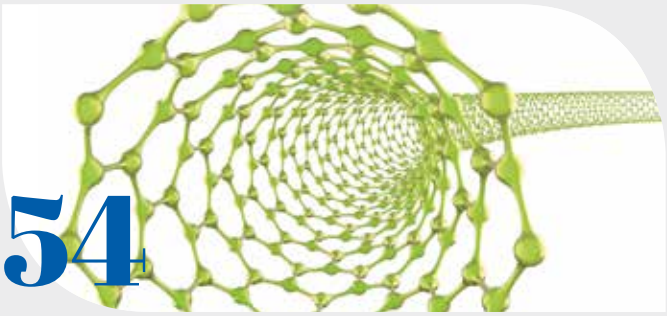

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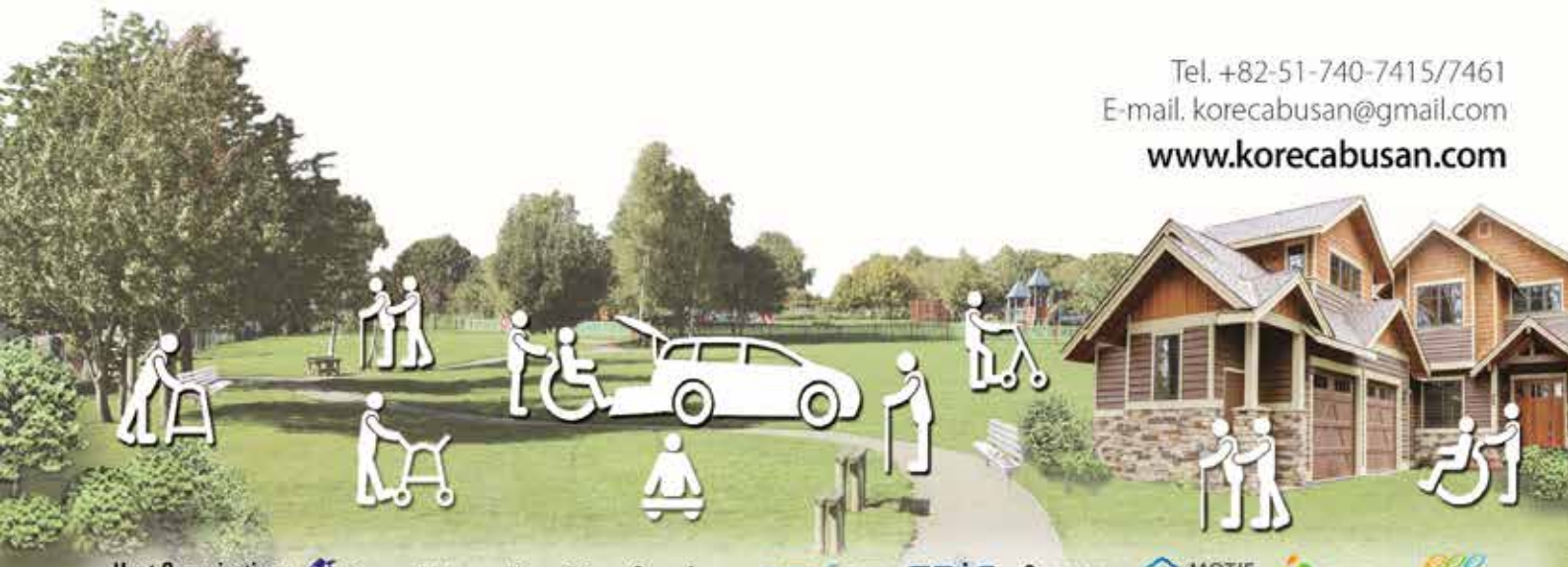

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focus on Latin AMERICA

Latin America and the Caribbean have led the developing world in shared prosperity achievements in the last decade, and have seen impressive poverty reduction successes, driven by growth, labor incomes and effective safety net programs. The middle class has expanded and the socioeconomic makeup of the region has transformed as a result. As the region now faces an economic slowdown and stagnating inequality, understanding what helped drive these gains becomes particularly valuable.

Author: Michela Adinolfi

FOCUS ON
Latin America

Cover Photo
Maya Temple At Palenque, Chipas, Mexico.
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Bolivia

In the last decade, Bolivia's economy has expanded by over 5% a year on average, one of the highest rates in the Latin American region and the highest in the country's recent history over the past 35 years. In 2015, growth is expected to remain around 5%, a very favourable statistic compared to the regional average that places Bolivia at the third place.

Despite the fact that Bolivia is still one of the poorest countries in the South American continent, since 2006 poverty has been reduced by 25% and extreme poverty by 43%. According to Alicia Barcena, head of the Economic Commission on Latin America and the Caribbean (ECLAC), Bolivia has implemented an important policy for redistributing revenue, improving minimum wages (87.7% increase from 2005 to 2014) and carrying on social programs for poverty reduction.

Ten years ago a referendum vote indicated public support for an increased state control over the hydrocarbons sector, and in May 2006, newly-elected president Evo Morales renationalized Bolivia's oil and gas industries. According to official data, the nationalisation of about 20 companies has given the Bolivian government control over around 38% of the country's economy.

The state control over key industries is a controversial issue for many international economic observers; however, Mrs Barcena highlighted that this fact does not always imply a loss of efficiency. A positive signal that international investors' confidence has not been hit by such fears comes from the fact that Bolivia attracted highest level of foreign direct investments, as a percent of GDP, in South America in 2013, for a total $2.03 billion compared to $1.3 billion in 2008. Foreign investments account for about 6.7% of GDP, that is estimated to reach $32 billion in 2014, a fourfold increase since 8 years ago.

The increased tax revenue and the buildup of reserves (currently more than 48% of GDP), left Bolivia room for developing macroeconomic policies without borrowing from the IMF and use these resources to increase public investment spending. Over the last 8 years, total public investment as a percentage of GDP has doubled and it will amount to $6 million this year, partly to offset the slowdown in private investment that decelerated by 13% in 2015 to $1.7 billion, compared with a 36% jump to $1.5 billion in 2014 from the previous year.

In particular, public spending on health, education, pensions and poverty alleviation programs rose by 45% in real terms, but did not fully keep up with overall growth in the economy.

Such impressive progresses, however, cannot leave in shadow the many unsolved issues that Bolivia is facing. According to the non-profit association Cordaid, in fact, with over 60% of the population living in the cities (over one million in Santa Cruz), "women, young people and migrants in the urban slums have insufficient access to education and employment, and they often lack basic services such as housing and sanitation". In these contexts, the impact of social programs is still too limited and hasn't yet significantly tackled the marginalisation of poorest urban slum dwellers.

Health profile: The economic progress still has to develop its effects on the overall health of the population and on the access to healthcare services. According to the WHO, reporting data from the Ministry of Health and Sports of Bolivia, the country has about 5,674 inhabitants that are victims of social exclusion in health. The poorest 10% of the population receives 4% of the national income, while the richest 10% receives 47.2%. The decentralization of fiscal resources to municipalities and governorships has resulted in a fragmented system that is in urgent need of reforms.

According to the New State Constitution, adopted in 2009, the Right to Health and the Right to Health Care are to be guaranteed for all Bolivian citizens.

Ecuador

From a peak of 7.9% growth in 2011, Ecuador's economy maintained positive growth rates of 5.2% and 4.6%. As reported by the International Business Times, the country's growth rate since 2000 has been 5.5%, second only to Peru (7%). During the first quarter of 2014 this strength has maintained with an annual GDP growth of 4.9%.

With a favourable debt-to-GDP ratio at 24%, the government has focused its macroeconomic interventions on a double priority of eradicating poverty and diversify the country's productive structure to generate a sustainable economy oriented towards knowledge and innovation.

Along this path, public spending increased from 21% of the GDP in 2006 to 44% in 2013, with the largest budget share allocated for investment programs in energy, infrastructure, and transportation, as well as in social sectors.

As regards the parametres related to inclusiveness of economic growth, Ecuador scored quite well among its neighbors. According to the World Bank, between 2006 and June 2014, poverty measured by income (using the national poverty line) decreased from 37.6% to 24.5% and extreme poverty was reduced from 16.9% to 8%.
Inequality has also been reduced at a faster pace than the regional average, as testified by the Gini's coefficient decrease from 54 to 48.6 between 2006 and June 2014. Over the 2000s decade, the income of the poorest 40% of the population increased in 8.8%, compared with the average 5,8% of the country, showing that economic growth benefited the poorer groups comparatively more than the others.

As usual, the positive outcomes go hand in hand with shortcomings that have yet to be solved. Poverty levels in rural areas remain high and the dependency not only of the trade balance but of the public investment financing the oil sector may bring some risks if the diversification efforts are not put into effect in a short term.

Health profile: As outlined in a recent study by Dana Rasch and Krista Bywater, the predominance of neoliberal, biomedical-based models of care led to years of disinvestment in the public healthcare system of Ecuador. As a result, healthcare became unaccessible and costly for the majority of Ecuadoreans. In 2006, the government changed policy and shifted to a public-led system increasing funding for the Ministry of Health ($1.6 billion in 2011).

The increased budget has been used to expand infrastructure in order to boost access to health services, building public hospitals and recruiting physicians. The MoH has focused not only on the immediate healthcare issues but also on the negative environmental conditions that create a basis for diseases' spreading. The measures taken by the government include both physical interventions, such as the installation of sewage systems and programs in disadvantaged communities that face serious health issues linked to poverty and marginalisation. The increased funding and the attention on social determinants of disease has expanded access to health services from 16 million patients treated in 2006 to 38 million in 2012. Infant mortality rate and children anemia are also decreasing at a rapid pace.

Mexico

Mexico's economy has been facing the consequences of a weak currency and low oil prices that reduced government revenues, so that in 2014 the economy grew below expectations by slightly more than 2%. Growth for 2015 is estimated around 3.5%, but the outlook is still uncertain due to weaker household spending and consumer confidence. The country is closely tied to the USA and has an export-driven economy (exports account for a third of GDP), therefore, the recovery of the US economy will benefit Mexico as well.

According to the World Bank, between 2000 and 2010, 17% of the Mexican population has joined the middle income ranks. Despite the persisting security problems and political unrest, from an economic point of view, Mexico is stable and its fundamentals are solid, with a macroeconomic management that "allowed the country to deal with financial volatility and changing investor sentiment without mayor liquidity pressures or the need for public intervention".

Health profile: The general health status of the Mexican population has improved from several programs aimed at making health services accessible to almost the whole population.
In 2003 was created a national low-cost insurance program known as "Seguro Popular", providing 49 million Mexicans, many of them working in the informal sector, with healthcare coverage that was previously impossible to obtain.

However, the public system often experiences poor quality and long waiting times, leading a consistent number of patients to seek private treatment, increasing their out-of-pocket expenses. The Economist Intelligence Unit recently estimated that about 45% of all health spending in Mexico (and over 90% of private healthcare spending) is paid directly by the patient at the point of delivery. Even more striking, out-of pocket expenses on drugs account for 83% of total drug expenditures, compared with 65% in China and 35% in the United States. For poorer individuals who cannot afford to pay the medical fees or drugs, the choice remains limited between lower quality care or no treatment at all, and this creates wide inequalities in access to healthcare among the different income groups.

MEXICO

The increased budget has been used to expand infrastructure in order to boost access to health services, building public hospitals and recruiting physicians.

Basic Statistics

Mexico

Statistics	
Total population (2013)	122,332,000
Gross national income per capita (PPP international $, 2013)	16,110
Life expectancy at birth m/f (years, 2012)	73/79
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2012)	177/90
Total expenditure on health per capita (Intl $, 2012)	1,062
Total expenditure on health as % of GDP (2012)	6.2

Ecuador

Statistics	
Total population (2013)	15,738,000
Gross national income per capita (PPP international $, 2013)	10,310
Life expectancy at birth m/f (years, 2012)	73/78
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2012)	159/87
Total expenditure on health per capita (Intl $, 2012)	652
Total expenditure on health as % of GDP (2012)	6.4

Peru

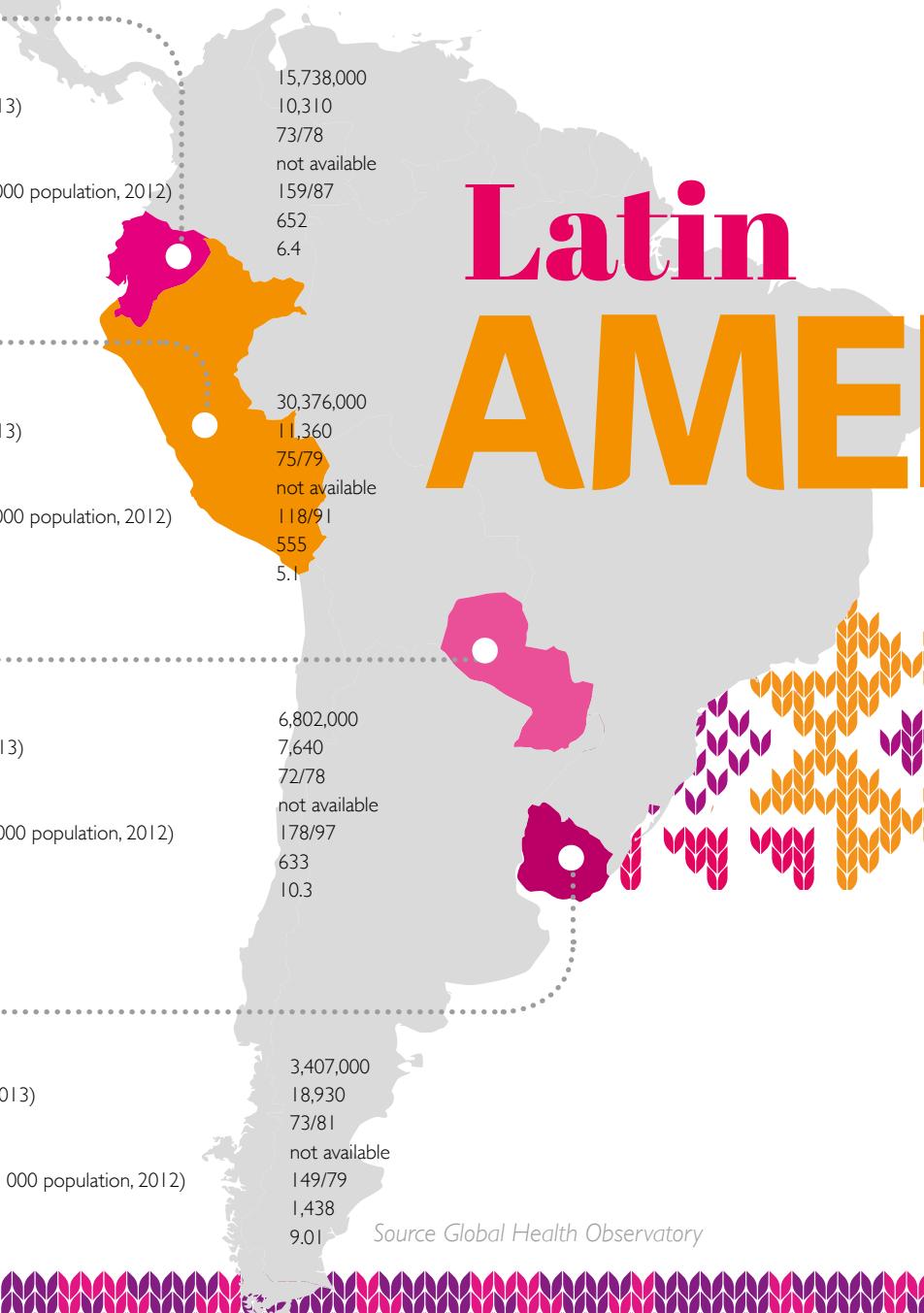
Statistics	
Total population (2013)	30,376,000
Gross national income per capita (PPP international $, 2013)	11,360
Life expectancy at birth m/f (years, 2012)	75/79
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2012)	118/91
Total expenditure on health per capita (Intl $, 2012)	555
Total expenditure on health as % of GDP (2012)	5.1

Paraguay

Statistics	
Total population (2013)	6,802,000
Gross national income per capita (PPP international $, 2013)	7,640
Life expectancy at birth m/f (years, 2012)	72/78
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2012)	178/97
Total expenditure on health per capita (Intl $, 2012)	633
Total expenditure on health as % of GDP (2012)	10.3

Uruguay

Statistics	
Total population (2013)	3,407,000
Gross national income per capita (PPP international $, 2013)	18,930
Life expectancy at birth m/f (years, 2012)	73/81
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2012)	149/79
Total expenditure on health per capita (Intl $, 2012)	1,438
Total expenditure on health as % of GDP (2012)	9.01



Source Global Health Observatory

ABOUT PAHO

The Pan American Health Organization (PAHO), founded in 1902, is the world's oldest international public health agency. It provides technical cooperation and mobilizes partnerships to improve health and quality of life in the countries of the Americas.

RICA

Regional Health Observatory

In lower middle income countries of the Americas, about 53% of deaths occurred before the age of 70 years old. In the Region of the Americas approximately 44% of total deaths occurred before the age of 70 years old. In lower and upper middle income countries about 52% of deaths occured before that age compared with 35% in high income countries, an excess of 17% of deaths. The interactive data visualization below shows the proportion of total deahts by under and above 70 years old, sex, income group of countries and causes of death.

In the whole region, 77% of deaths are due to Chronic-Non Communicable Diseases, having cardiovascular diseases as responsible for the larger proportion of non communicable disease deaths with 40% of deaths, followed by malignant neoplasms (25%), chronic respiratory diseases (8%), diabetes (6%), digestives diseases (6%) and 15% of deaths in the rest of non communicable diseases.
From the 44% of deaths under age 70, Non communicable diseases were responsible for 65% of deaths having cardiovascular diseases and malignant neoplasms as responsible for the largest proportion of death (32% each one), followed by digestive diseases (9%), diabetes mellitus (7%), respiratory diseases (6%) and having 13% of deaths in other chronic non communicable diseases.

Source Pan American Health Organization (PAHO)

Life expectancy

75 years
is the average life expectancy at birth of the Americas' population in 2009

Deaths

13%
of deaths in the Americas are due to Ischemic Heart Diseases

An additional burden on the healthcare system is given by the changing demographic and epidemiological patterns. Despite the young population with a 30% share of children under 14, the elderly group is expected to grow fast and by 2016, 7.5% of the population will be 65 years or older.

Obesity is becoming a major issue for about a third of the population, due to lifestyles and food habits, and diabetes is expanding at three times the rate of population growth (according to the Federacion Mexicana de Diabetes, INEGI). Cancer, heart diseases, high cholesterol and hypertension, all chronic diseases common in developed countries, are all posing a rising threat to the health of the population and weighing on the health system. Currently, more than half the public healthcare funds are spent on non-communicable diseases, with about 20% focused just on diabetes.

In order to face the challenge, the government's National Development Plan for 2013-2018 established a series of initiatives to allow access to any facilities irrespective of what healthcare provider or insurance system they belong or are contracted to.

Moreover, Mexico needs to increase its healthcare workforce and infrastructure: in comparison with OECD average, it has 2-3 times fewer specialists considering its epidemiological profile, and it only counts 16 hospital beds per 10,000 people, compared with 41 for Argentina and 24 for Brazil.

Inequalities among the different systems also impact on the availability of care: for instance, the Pemex system spends almost 9 times as much per capita as the Seguro Popular.

On the other hand, richer states such as the Federal District register 6 times more specialists and 3 times more hospital beds than poorer states such as Chiapas.

The World Bank is financing some interventions to enhance the Mexican healthcare infrasturcture: As reported by the Economist Intelligence Unit, Hospitaria recently built a 50-bed "green" hospital north of Monterrey that caters to low- and middle-income families.

More small and mid-sized hospitals (50-100 beds) are being built and integrated into the Mexican Hospital Consortium (CMH), which is developing a platform to promote the joint purchase of medical equipment and medicines.

Paraguay

Paraguay is endowed with many natural resources and an important production of clean energy due to the abundant reserve of fresh water formed by the Guaranì acquifer. Agriculture and livestock production are the core economic acrivities, and soy and beef alone account for about 40% of the total exports. Titanium, iron ore and recently discovered oil reserves also created new possibilities for the mineral sector. Despite the economy is very open, the greographic isolation and poor transportation infrastructure creates difficulties in expanding the industrial network.

In the last decade, Paraguay progressed major social reforms such as free access to primary health care and basic education, and the expansion of conditional cash transfer programs with impact on the most vulnerable populations. Nevertheless, of the 6.8 million inhabitants, around a quarter of the population live in poverty, one of the highest rates in Latin America. GDP growth is estimated at 4.5% to 5% for 2014, and almost no variation is expected for 2015.

It is important to note that the Paraguayan legislation protects strategic investments and the government is favouring projects that target the unpopulated, unexploited regions that are unfit for agricultural or farming activities, due to the presence of mineral resources.

The European Commission will provide a total of €168 million of development cooperation support to Paraguay in the period 2014-2020 to improve education, enhance business environment and strengthen the social protection system and the democratic institutions.

€85 million will be allocated to support the implementation of the national educational policy; €20 million will go to private sector development, to create a competitive private sector by supporting SMEs with high potential to export.

€84 million will be devoted to social protection and target extreme poverty reduction, contributing to expand the access to basic public services (health, education, justice) and employment opportunities, and to strengthen the quality of public service delivery.

€10 million will be used to promote democracy, participation and institutional strengthening.

Health profile:
In Paraguay there is a mixed health system made up of stratified subsystems, roughly corresponding to the socioeconomic classes. Public sector provision is dominated by the Ministry of Health and the Social Insurance Institute (IPS), a half public - half private institution financed by employee and employer payroll contributions, currently covering about 15-20% of the population.

In total, around 95% of the population has access to public healthcare provided by the MoH and IPS, 75% of which is not covered by any insurance (private or public). The MoH runs 1,028 health centres, 354 of which also offer inpatient care, while the IPS has 78 health centres, and 41 are inpatient centres.

The private, for-profit sector provides healthcare to 7% of the population, and its facilities are mostly located in the urban areas of Asunción, Central and the other larger cities.

Expenditure on health is 7% of GDP, with private spending accounting for about 57% of the share. Out-of-pocket expenditure represents 85% of private health spending, and within these direct payments, 58.6% are for drugs. This reflects a lack of effective protection for poorer households that spend proportionately more on health directly out of their income.

Life expenctancy is 72 years, two years less than the Latin American average.

Despite the infant mortality rate was significantly reduced from 30 to 15.4 for 1,000 live births between 1990 and 2009, the maternal mortality rate actually increased in the same period to 150.1 for 100,000 live births in 1990 to 125.3 in 2009. This shows a shortcoming in maternal care that has been targeted by the government's implementation of a new primary healthcare system implemented from 2008 to 2011. During this period, 704 Family Health Units (USF) were installed in 234 districts, starting from those with the highest poverty rate, for a total populatoin of 2.46 million. These units, staffed with a doctor and two nurses, provide primary healthcare services to a basin of 3,500-5,000 people, especially focusing on rural inhabitants.

Government efforts to increase the availability of health services to the population have increased in the last few years, reaching a figure of 22.5 health workers per 10,000 population as a national average, but they are very unequally distributed: due to lack of infrastructure and incentives to work in rural areas, 70% are concentrated in the area around Asunción where 30% of the population lives.
Moreover, there is an unbalanced density of 2 physicians for every nurse. Other issues include health worker migration, inadequate training for the needs of the primary health care system and weak regulation and control of professionals in private sector institutions.

Peru

With a population of 30.3 million, Peru is the 7th largest Latin American economy, and one of the best performing during the last five years. Only in 2014 growth slowed down to 2.4% from 5.8% registered in 2013, due to weaker demand and low prices for commodity exports and internally, to lower investments and private consumption. The government is undertaking large public-private infrastructure projects, co-financed through the Agency for Promotion of Private Investment (ProInversion), including:
• the Peruvian National Fiber Backbone project, aimed to connect rural villages to broadband services;
• construction of 54 schools (42 in Lima);
• construction and maintenance of general hospital services at Cayetano Heredia Hospital Huaycan, Hipolito Unanue, and Sergio Bernales hospital.
• solid waste management in health facilities of the Metropolitan of Lima;
• construction of the Center for Radiation, a comprehensive provision of clinical pathology in Lima, and the construction of the National School of Public Health;
• improving the transportation system through the Peripheral Ring Road, Highway Tarma-La Merced, and the Central Economic Corridor.

Currently, nearly 60% of GDP comes from the services sector, primarily telecommunications and financial services that account for nearly 40% of GDP. Industry follows at 35% of GDP, and its recent modernization has created more employment. In the last few years domestic demand has been the main driver of growth, sustained by a series of budget surpluses originating from fiscal consolidation, that allowed for productive public expenditures. The combination of natural resources, economic modernisation and political stability helped Peru emerging as one of the most stable economies in Latin America.

PERU

Peru has opened new markets through several bilateral and multilateral trade agreements, starting from joining MERCOSUR in 2005

PARAGUAY

The private, for-profit sector provides healthcare to 7% of the population, and its facilities are mostly located in the urban areas of Asunción, Central and the other larger cities.

As regards foreign trade, Peru is an exporter of commodity goods and an importer of industrial goods, which exposes it to price volatility. However, Peru has opened new markets through several bilateral and multilateral trade agreements, starting from joining MERCOSUR in 2005, and it signed bilateral treaties with other Latin American and Caribbean economies. In addition, the United States-Peru Trade Promotion Agreement (PTPA) has been operative since 2009.

Health profile: According to the WHO, Peru's recent good economic performance was fruitfully used to increase targeted social spending and programs, resulting in a marked improvement in key health indicators:
• reduction in extreme poverty from 23% to 12.6% (1991-2008);
• reduction of infant mortality from 53 per 1,000 live births to 17 per 100 live births (1993-2010);
• reduction in chronic malnutrition from 26.5% to 17.9% NCHS (1999 – 2010).

Peru has a decentralized health care system administered by:
1. Ministry of Health (MINSA), which provides health services for 60% of the population;
2. EsSalud, which provides for 30% of the population
3. The Armed Forces (FFAA), National Police (PNP), and the private sector together provide services to the remaining 10%.
The presence of multiple providers of services and insurance creates a high degree of overlap and little coordination, with health professionals working across different subsectors at the same time.

The migration of health workers to foreign countries did not impact on their general increase in the country, but there was also an increased need for specialists due to the implementation of universal health insurance and associated policies.

In Peru as well as in the other Latin American countries, inequitable geographic distribution of health workers remains one of the main challenges to reach the universal coverage. Lima and the coastal areas have the highest densities of health workers, while the areas of Piura, Lambayeque and Loreto have the lowest. Since the implementation of the SERUMS plan to distribute and retain health workers in remote areas, these differences have begun to decrease.

Other issues remain the low public financing of healthcare, the persistence and increased risk of both communicable and non-communicable chronic diseases, adolescent pregnancy and high prevalence of MDR tuberculosis and TB, concentrated in Lima and Callao.

Uruguay

The Economic Commission for Latin America and the Caribbean (CEPAL) reported a 6.5% poverty rate in Uruguay for 2011, the lowest rate in the region. Uruguay is also known as the "Netherlands of Latin America" due to its liberal, consolidated democratic system and stable economy.

In fact, the Uruguayan economy hasn't fallen into recession for 12 years now, if the IMF's prediction of 3.5% growth in 2014 is confirmed. This figure would mark a slowdown compared to the 4.4% expansion in 2013, but considering the average annual growth rate of 6% registered between 2005 and 2013, and the GDP's record high of almost US$50,000 million, that cannot be questioned.

The investors confidence is confirmed by Uruguay's rank as the country with the third-highest foreign direct investment (FDI) inflow in South America (5.4% in terms of GDP).

This is also due to a legislation (Law No. 16,906 on Investment Promotion and Protection enacted in 1998) that guarantees to foreign investment the same treatment as national investment.
Against such positive background, there are some contingent risks given by high inflation (8.5%) and rising (although still low) unemployment at 6.4%

Health profile: Uruguay is claimed to have one of the best functioning welfare systems around the world. It is based on a National Integrated Healthcare System (SNIS) that uses both public and private providers. They include:
• Public providers funded by the govermnet (ASSE - Administración de Servicios de Salud del Estado) and accessible through public health insurance (Seguro Nacional de Salud - SNS);
• Private, not-for-profit institutions, mainly medical cooperatives or "mutualistas" (IAMC - Instituciones de Asistencia Médica Colectiva);
• Private insurances (Seguros Privados Integrales)

URUGUAY

The public sector has been decongestioned and the pressure on budget diminished; the gap between the ability to access health services among the different socio-economic strata has narrowed.

The State Health Services Administration (ASSE) serves about a third of the population and the related agencies (such as the Armed Forces, Police, etc) serve 7.2%. The IAMC ("Mutualistas" or "Cooperativas" provide healthcare to about 47% of the population through private health insurance plans. The public health insurance can also be replaced with direct subscription to a specific Mutualista through monthly fixed fees (plus small co-payments).
With this system, 96.3% of population is affiliated to a healthcare provider, either the IAMC, ASSE or private insurer.

The results are generally positive: the public sector has been decongestioned and the pressure on budget diminished; the gap between the ability to access health services among the different socio-economic strata has narrowed, and all income groups have increased the share of people covered by a public or private insurance.

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Outlook on ISRAEL

An outlook on Israel's healthcare system and life sciences industry

Author: Michela Adinolfi

Economy

In a recent report, Espicom forecasts Israel's real GDP to grow by 3,2% and 3.5% in 2014 and 2015, respectively. While exports are improving, led by accelerating growth in the eurozone and the US, the domestic economic growth will remain sluggish, with private consumption remaining at the same levels of GDP growth during 2015 and government spending on public services limited by austerity policies. Unemployment rate is expected to peak at 6.7% in 2014 and return to approximately the same average of 2013 during 2015 (6.5%).

Over the 2014-18 period, a moderation of austerity policies combined with increasing exports and low inflation are expected to rise real GDP growth up to 4%. Despite the Israeli economy is strong, some risk factors remain the tense political climate, as negotiations with Palestine proved inconclusive so far, and the lower-than-average performance in business transparency, bureaucracy and legal diligence ratings among the OECD countries.

Healthcare

Population healthcare status

According to the "Industry Report Healthcare Israel", health indicators in Israel are good, as life expectancy (81.4 years in 2013) is the highest in the Middle East region and the infant mortality rate (3.6 per 1,000 live births in 2013) is comparable with other developed economies. Nevertheless, there are significant disparities between different communities.

The Arab community shows a prevalence of diseases typical of developing economies, while the wealthier groups are increasingly affected by obesity and other lifestyle issues, such as diabetes and heart disease. Moreover, birth abnormalities are more common in certain low-income sectors of the population including ultra-Orthodox Jewish and Arab populations.

Health system organisation

Israel has a universal healthcare system with generally high quality standards. The Ministry of Health provides and co-ordinates health services, and it is responsible for the health legislation and the maintenance of medical and drug quality standards. Patients are entitled to choose their doctors, hospitals and other medical services from a list of providers, including the health ministry, the municipalities, private profit-making and non-profit bodies and the health-care funds.

Public health services, operated by district and regional health offices, include dental care, environmental health administration, epidemiology and laboratories, food service, mother and child care, and health education.

A key advantage of the Israeli healthcare system is the high standard of primary care, due to a prioritization policy carried out over the last two decades. Patients generally use primary health clinics as first point of call and they are gatekeepers to hospitals and specialist care. 24-hour hotlines, evening and urgent care services and home visit services contribute to reduce the burden on the secondary and tertiary care level. Moreover, information technology platforms help patients suffering from chronic conditions to perform self-monitoring tasks and ensure regular check-ups.

Among the major strengths of primary care in Israel, there is the extensive range of data collected by community health facilities on nearly the entire population through electronic patient records based on the specification of a minimum data set called the Quality Indicators in Community Health Care (QICH) programme. The QICH includes basic patient demographics and 35 measures across six key areas, identifying some risk factors for poor health (e.g. obesity), monitoring the quality of care being delivered, tracking drug utilisation and measuring selected treatment outcomes.

Israel was also an early adopter of Health IT and telemedicine, with almost 20-year implementation expertise. It was one of the first countries to introduce electronic clinical decision support systems and online indicators for medical and service quality. Currently, Electronic Medical Records (EMR) are used by 99% of primary care physician in Israel, while the use of Computerized Physician Order Entries (CPOE) and E-Prescribing is estimated at 95%.

Another peculiar feature is the prevalence of healthcare teams over solo practitioners. Teamworking has been actively encouraged by the healthcare institutions by promoting larger clinics with doctors salaried by the managing health fund, and partly also through financial incentives for independent practitioners to collaborate with healthcre teams. This is a significant difference from other OECD countries' health systems where a large proportion of doctors

Cover Photo
Tel Aviv and Ramat Gan Skyline at sunset
Dmitry Pistrov shutterstock

continue to work as solo-practitioners. The average primary care clinic in Israel is staffed by the equivalent of 3.4 general practitioners, 2.6 nurses, 1.5 practice assistants and most have a practice manager.

However, despite the strong focus on primary care, the overall occupancy rate in Israeli hospitals is 97%, the highest of all OECD countries that report an average of 76%. On the other hand, the average length of stay is 4.3 days, well below the OECD average of 6.5 days.

Hospitals are divided into four main categories: general care hospitals, psychiatric care hospitals, long-term (chronic) care facilities and rehabilitation units. In 2013, there were an estimated 374 hospitals in Israel, 188 managed by the public sector and 185 by the private sector. Israel has approximately 44,000 hospital beds, with a ratio of 5.7 per thousand population, much higher than the Middle East and Africa average of 2.3; over half of these beds, as well as most preventive health services, are provided directly by the Ministry of Health and financed by the state budget with around 25% of the total for general hospitals and 50% for mental hospitals.

In 2013, there were around 1.4 million inpatient admissions to Israeli hospitals, with an inpatient rate per thousand population of 178.4, much higher than the 79.7 average for the Middle East and Africa region in 2013.

In terms of ambulatory care, there were an estimated 35.3 million outpatient visits in 2013. The outpatient rate per thousand population was again much higher than the Middle East and Africa average (4,568.3 against 3,108.1 per thousand population).

Several hospitals are run by private associations with their own health funds. The role of the private sector is expected to grow along with the efforts to cut operating deficits, most likely by turning an increasing number of hospitals into financially independent, privately-funded institutions in the future. Yet this measure, as well as the possibility for public hospitals to offer private treatment, aren't universally welcome. Moreover, both public and private hospitals attract medical tourists particularly from the US and Eastern Europe, but this caused some concerns that high-paying foreign customers may be prioritised, thus diminishing the standards of care available for Israelis.

Health Insurance

Israel has a tax-funded national health insurance that provides universal healthcare coverage. Israelis choose among four competing health insurance funds, which must offer insured people a basic package of health services. In order to access these service, all residents need to pay the health insurance tax (a progressive contribution paid out of salary integrated by state funding) and to register with one of the four non-government, not-for-profit health maintenance organisations (HMOs) that provide medical services. Each health fund receives a yearly per capita allocation from the government, adjusted for age, gender and location of the people insured. According to the OECD, the two largest funds (Clalit and Maccabi) cover around 80% of the population. The health funds may either run the cinics they own directly or by contracting with independent providers and among the four funds, Clalit runs the largest number of facilities.

The standardised healthcare package includes ambulatory care and hospital services, but around 75% of the population adds a supplementary insurance from one of the four health insurance

funds to cover services outside the basic package. The government is tyring to guarantee equitable access to healthcare, for instance it has lately extended the insurance basket to 83 medicines and medical technologies, at a total cost of US$86.8 million. Yet, about one third of the population buys commercial health insurance to cover extra services such as dental care, ancillary services, and to choose their private provider. A further two-thirds of the population also purchases commercial insurance for long-term care.

Healthcare funds accounted for only around 33% of total health services in 2012 (compared with 43% in 2003), with private doctors, dentists and other private medical entities and market producers providing 56%, and various non-profit institutions accounting for a further 11%.

Healthcare Spending

Unlike most OECD countries that have been facing rapidly rising healthcare costs, Israel's healthcare spending has remained among the lowest until recent times, at about 7.6% of GDP in 2013, equal to US$20.4 billion or US$2,636 per capita (Espicom estimate).

Around 64% of this amount is spent in the public sector, while the remaining 36% is private (a slight decrease from 2012, when it accounted for 38.3% of total health spending according to the WHO). Of this share, out-of-pocket payments made up 65.3%, while private health insurance accounted for 26.5%. Private spending mostly covers dental care (although children are supposed to receive it for free), co-payments on medications and the cost of supplementary insurance.

With an estimated average population growth of 1.7% a year, per capita health spending is forecast to reach US$3,759 by 2018. This means an average total health expenditure growth of 9% in US dollar term.

A pressing issue for Israeli's healthcare financing is the increasing deficit of the health funds, which amounted to US$570 million in 2012, a 50% increase on the previous year. Further financial pressure is expected in the near future due to the extension of healthcare coverage to thousands of Palestinians living in Israel under family unification arrangements, and to the rising elderly population and incidence of chronic diseases, requiring to add more treatments to the insurance package.

PHOTO
Next Page
Tasting figs at the market.
A man shopping for fresh fruits, is tasting a fresh fig in a market stall at the famous Mahane Yehuda Market in dowtown Jerusalem.
MaestroBooks / istockphoto

Healthcare Personnel

In 2013, there were an estimated 23,930 physicians in Israel, with a ratio of 3.1 per thousand population. This rate is twice the Middle East and Africa average (1.5 in 2013), and it compares well with other developed countries (3.5 per 1,000). The high number of doctors and dentists partly reflects the immigration of physicians from the former Soviet Union during the 1990s. However, as these doctors reach the retirement age, there may be a potential shortage of medical professionals. This is also confirmed by OECD's estimate of 70% of Israel's licensed physicians and nearly 60% of nurses beign aged over 45.

Israel used to rank quite low in terms of young graduates (4.99 per 100,000 population, compared with an OECD average of 10.6) and nurses (4.8 nurses per 1,000 people, compared to the European average of 8.8).

Despite the efforts to improve these figures are commendable, the government needs to support healthcare personnel employment in primary care settings rather than in hospitals or specialised care, while at the same time introducing stronger measures for continuing professional development to guarantee that the skills of the older medical workforce remain current.

For instance, around 55% of nurses have at least a first degree, and one-fifth of these also have a higher degree. The government is making efforts to promote further academic training, but they should be compensated by policies aimed at guaranteeing a sufficient number of nurses in community and primary care facilities, particularly in disadvantaged areas, to prevent the deepening of health inequalities.

Health system issues and challenges

• Deep-rooted inequalities. The substantial inequalities between the Jewish and non-Jewish population, which also includes the poorest groups, are generally the result of interconnected geographic, socio-economic and ethnic factors. Therefore it is difficult to tackle the related health outcomes without intervening on the roots of the issue.

The Arab population, concentrated in the northern and southern parts of the country, is the largest non-Jewish group in Israel, and generally poorer than the Jewish population. This reflects in poorer health outcomes: lower life expectancy and higher infant mortality rates, as well as in higher probability to suffer from diabetes, hypertension, heart attacks and strokes.

Deep-rooted inequalities. The substantial inequalities between the Jewish and non-Jewish population, which also includes the poorest groups, are generally the result of interconnected geographic, socio-economic and ethnic factors.

PHOTO
Jerusalem.
Jerusalem at dusk, view from the Olive Mountain.
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Even within the Jewish population there are great disparities, with mortality for Jews born in Asia, Africa and Europe up to 70% higher than among Israeli-born Jews, and pockets of poverty concentrated among Ultra-Orthodox Jews, who often also have distinctive health behaviours.

• Uneven distribution of health resources. The different density of health workers may be taken as an instance of the different availability of health services across the country: Jerusalem and Tel Aviv have 16.4 and 18.4 health care staff per 1,000 workers, compared to 11.2 and 10.0 in the North and the South respectively. Combined with the lower economic status, peripheral areas experience higher unmet demand for health services and lower resources. To fill this gap, the government has introduced a "remoteness factor" into the formula for allocating public health insurance funds to the four funds, aimed at rewarding health funds with population living in more remote areas. Some further actions include the establishment of a new medical school in Galilee (North) and efforts to increase the number of hospital beds in peripheral regions, as well as incentives to promote health programs among disadvantaged populations and to attract health personnel in these areas.

• Rising out-of-pocket costs. Israel is one of the OECD countries with the highest out-of-pocket expenditure as a share of household consumption. Lower incomes are much more affected by this trend which may prevent families from seeking even necessary treatments, impacting on long-term health outcomes. Areas of intervention may be the extension of the insurance basket and preventative services for households in higher need, at the same time avoiding to increase co-payments for essential health services.

Life Sciences Industry

Israel has achieved significant, internationally renown results in scientific research, medical device and bio-pharma patents, stem cell research and therapeutics, with a rich pipeline of R&D companies and multinationals such as Johnson & Johnson, Perrigo, GE Healthcare, Phillips Medical, Abbott Laboratories, Merck Serono and Sanofi. Furthermore, the technological incubator network, with more than 20 incubators throughout the country hosting up to 15 companies each, has proved to be an effective tool for encouraging research and development in the life sciences, providing start-ips with secretarial, legal and business development services. The incubator provides funding of approximately US$500,000 for the first 2-3 years of the life of the company, helping it overcome the highest risk phase and scarce private funding. The program has been active since the early 1990s and 1000 companies had already graduated by 2012. They have reached the stage of independent, external funding and around one-third of them have already begun to generate revenue.

In 2011 life sciences exports reached US$8.9 billion, an increase of 10% over 2010. The total value of the industry was estimated at US$327 billion in 2013 and it is forecasted to reach US$434 billion in 2017. Medical devices account for the largest share of the industry (62%) followed by Biotechnology and Pharmaceuticals (both 12%) and Healthcare IT and Life Sciences services (both 7%).

The Medical Device Market

Highlights

• Healthcare expenditure estimated at US$2,687 per capita in 2013 and 7.8% of GDP.
• Population estimated at 7.7mn in 2013, with a rapidly growing elderly demographic contributing to rising healthcare costs and the burden of non-communicable diseases.
• In 2013, Israel had 374 hospitals, and a ratio of 5.7 hospital beds and 3.1 doctors per 1,000 population;
• Second largest medical device market in the region, with a strong and advanced local industry but mainly export-oriented;
• 83% of the market still supplied by imports.

According to a recent Espicom report, Israel has the highest rate of registered medical device patents per capita in the world, with cutting-edge innovations that have already been adopted worldwide and some others that are still undergoing clinical trials. Israel is the second largest medical device market in the Middle East region after Saudi Arabia, estimated at US$1,099.4 million, or US$141 per capita.

The market is expected to expand by around 7% annually over the next three years, reaching US$1,570.9 million, or US$186 per capita by 2018.

The country has a strong medical device production, estimated at around US$2 billion in 2012. The domestic manufacturing industry is mainly export-oriented, with US$1,738.1 million exported in 2012 (+3.7% compared to 2011), half to the USA and the rest mainly to Germany and China. Given the isolation of Israel from the neighbouring Arab countries, trade with the EU and the USA plays a dominant role in virtually all industry sectors.

The USA and Germany are not only leading export destinations, but also leading suppliers of imports to Israel, who is heavily dependent on imports to supply over 80% of the market: in 2012, they accounted respectively for 31% and 10% of total imports, for a combined total of US$328.2 million. Other key suppliers included China, Japan and

Switzerland, while the European Union as a whole supplied a third of the total at a value of US$268.5 million. High-end products, especially electromedical and diagnostic imaging apparatus, account for the largest import share in value terms.

Medical device market by product sector, 2013

Sector	Market size, Us$ mn	Market Share, %	Main supplier
Diagnostic Imaging	**332,5**	**30,2**	
Electrodiagnostic prod.	*134,7*		*USA, China*
Imaging parts/access.	*148,1*		*EU, USA*
Radiation apparatus	*49,7*		*USA, Germany*
Other medical devices	**284,8**	**25,9**	**USA, EU**
Consumables		**18**	
Dental Products	**77,3**	**7**	
Instruments and supplies	*70,6*		*EU*
Drills, chairs, x-ray	*6,7*		*USA, Japan, China, Germany*
Orthopaedics and prosthetics	**50,1**	**4,6**	**USA, Germany**
artificial body parts	*27*		
artificial joints and	*11,3*		
Patient Aids	**156,7**	**14,3**	
hearing aids/pacemakers	*112,5*		*USA, Switzerland*
therapeutic appliances	*44,2*		*China, Usa*

Medical Device Imports

In 2012, imports grew by 2.7% to US$ 798.2 million, while in the 12 months ending June 2013, the value of medical device imports climbed by 3.7% to stand at US $828.4 millioin. This growth was fuelled by strong growth in both the consumables and diagnostic imaging categories. The pace of growth accelerated in the three months ending June 2013, when the value of medical devices stood at US$225.5 million, with a 16.6% increase on the same three month period in 2012.

Sector	Import value, Us$ mn	Share of total imports, %
Consumables	**159,3**	**20**
syringes/needles/catheters	*113*	
Diagnostic Imaging	**235,4**	**29,5**
electrodiagnostic apparatus	*106,5*	
radiation apparatus	*28,7*	
imaging parts & accessories	*100,3*	
Dental Products	**50**	**6,3**
capital equipment	*5,1*	
instruments & supplies	*45*	
Orthopaedics and Prosthetics	**41,3**	**5,2**
Patient Aids	**132,7**	**16,6**
portable aids	*98,5*	
therapeutic appliances	*34,2*	
Other Medical Devices	**179,4**	**22,5**
hospital forniture	*14,9*	
ophthalmic instruments	*13,4*	

Medical Device Exports

In 2012, after a slowdonwn period following 2009 crisi, medical exports grew again to total US$1,738.1 million. Between 2007 and 2012, export sales had a CAGR of 5.2%. In the 12 months ending June 2013, the value of medical device exports climbed to US$1,768 million, a 2.5% increase on the same 12 month period ending in June 2012. Diagnostic imaging and patient aids were the only two categories to post a decline.

Sector	Import value, Us$ mn	Share of total imports, %
Consumables	**159,3**	**20**
syringes/needles/catheters	*113*	
Diagnostic Imaging	**235,4**	**29,5**
electrodiagnostic apparatus	*106,5*	
radiation apparatus	*28,7*	
imaging parts & accessories	*100,3*	
Dental Products	**50**	**6,3**
capital equipment	*5,1*	
instruments & supplies	*45*	
Orthopaedics and Prosthetics	**41,3**	**5,2**
Patient Aids	**132,7**	**16,6**
portable aids	*98,5*	
therapeutic appliances	*34,2*	
Other Medical Devices	**179,4**	**22,5**
hospital forniture	*14,9*	
ophthalmic instruments	*13,4*	

Sources:

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A K.P.I. analysis for the Health Technology Management in hospital.

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Introduction

Technology innovation has provided real advances in healthcare during these last years with the consequent proliferation of technology in healthcare. Hospitals equipment complexity has reached higher levels of management expenditure in spite of limited economic resources[1]. Therefore, it is necessary to rationalize the acquisition of new technologies considering many factors related to the devices. Additionally, optimization of maintenance costs, devices usage, and risk management is necessary. For this reason, the equipment planning decision-makers in hospital need new methods for efficient and appropriate analysis of health-care technology by reducing the replacement and management costs.

Furthermore, the Health Technology Management is strongly depending on the hospital area where the device is used such as the presence of patient or not, on single hospital resources and on "clinical needs" given by the necessity to compete with other local health structures in technological innovation.

Indeed, this study aims to propose a methodology which takes into consideration all these aspects through the analysis of accessible databases by using a set of Key Performance Indicators (KPI) in order to provide safety and technical information for equipment replacement and management[2]. Appropriate KPI are necessary in order to evaluate as well as technical, usability and economic aspects related to the medical devices with a sustainable methodology for a complete hospital based technology management.

Method

The set data is obtained from the large Italian hospital which includes all the maintenance data of 15,000 medical devices from 2000 to 2007. Only data from purchased devices has been considered in order to have a complete and homogeneous data deriving from the same management and maintenance protocols.

According to different health structures' needs, the proposal for a general technology management method is essential in order to define the most appropriate and objective KPIs for a quantitative evaluation of safety, usage, reliability and costs of medical equipment management and acquisition.

A "3-step" methodology has been developed for the analysis concerning the 'data organization', the 'medical devices classification' and the 'KPI analysis'.

Data organization

The first step has been to gather all medical devices under homogeneous classes of technology to allow comparisons among different model equipment and organizations. Italian Classification of Medical Devices code 'CIVAB' has been followed for categorization. Possible conversions are feasible to pass from CIVAB to GMDN classification (Global Medical Device Nomenclature) or to the UMDNS classification of the ECRI (Emergency Care Research Institute).

The CIVAB classification uses a seven letter code, where the first three letters are typical for technology and the others define the manufacturers and the specific model. An example is reported in Table I: the 'ECG' code includes all the devices for normal electrocardiography.

Only the first part of the code has been used in the analysis by considering only the technology type for a single medical device.

Table I. Technology code according to the Italian categories CIVAB

Technology Code	Medical Device Description
CIS	Cystoscope
DUS	Duodenoscope
ECG	Electrocardiography
EEG	Electroencephalograph
ENS	Encephaloscope

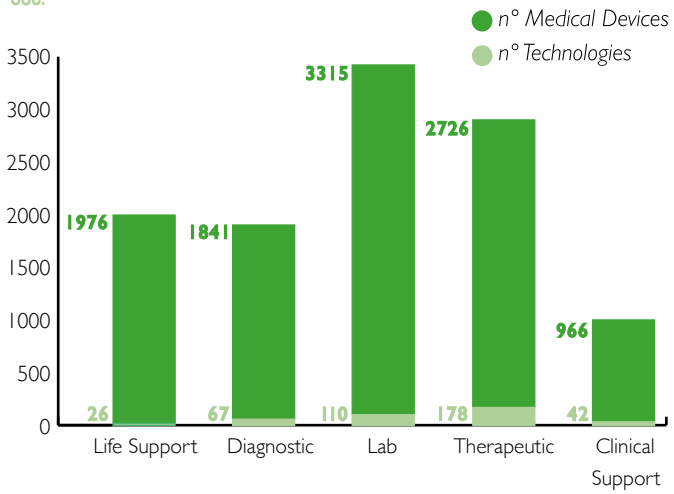
Medical Devices classification

The second step of the analysis is the classification of medical equipment according to their *"destination of use," "technology level"* and *"maintenance costs."* It has been necessary to use the non-standard classification of medical devices in order to consider the working area where the device is used. This new classification allows a "context-aware" characterization of the device depending on its users and possible consequence on patient safety[3], good for the decision-makers because of the heterogeneous and diverse needs according to different hospital areas. It further underlines usability aspects depending on both the technological complexity of the device and the criticality of the area where the device is used. Suggestions by the Italian Ministry of Health have been followed to classify all medical devices according to their own destination of use in healthcare. Five "Destination of Use" have been considered: *Life Support, Diagnostic, Therapeutic, Laboratory and Clinical Support.* The category *'Clinical Support'* has been created in order to eliminate data degradation in the analysis given by the presence of not strictly clinical devices such as printer or lamps.

Classification of technology according to *"Technological Complexity"* is fundamental in device management, for instance in order to plan which maintenance activities are feasible for hospital biomedical technicians and which ones have to be requested as

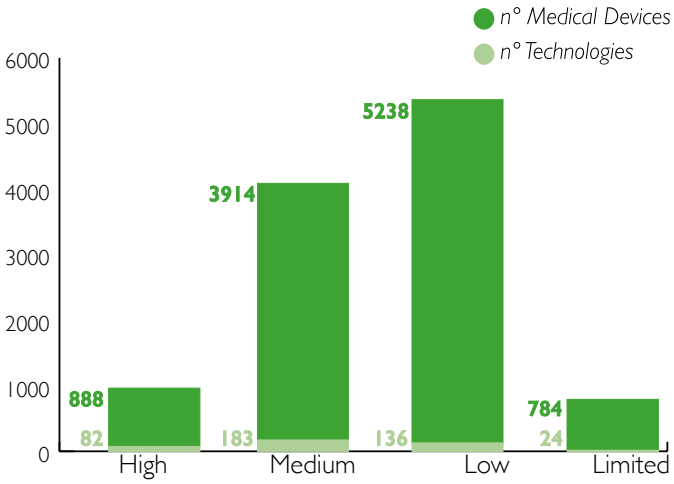
external services. Optimization of medical personnel and technicians' activities in relation to external private interventions is basic for a well-planned technology management.
These classes have been defined using only technical criteria, such as: use of radioactive materials, age of technology, device miniaturization level, presence of software and integration of different technologies in the same equipment. Four classes have been identified: *'High-,' 'Medium-,' 'Low-'* and *'Limited-Technology.'* Limited-Technology is defined in order to eliminate possible data degradation during the analysis because of the presence of not proper technological devices such as beds or wall units, that could contaminate the results. The outcomes of this analysis are the number of technologies and the number of devices, both reported in the graph, see Figure 1.

Figure 1. Classification of medical devices according to the Destination of Use.



The classification phase must consider the evaluation of device technical maintenance costs[4],[5] by classifying the devices depending on "Maintenance Incidence Ratio" (MIR), that is defined as "maintenance costs/acquisition cost[6]". Four categories were defined: *High, High-Medium, Medium-Low and Low,* see Figure 2.

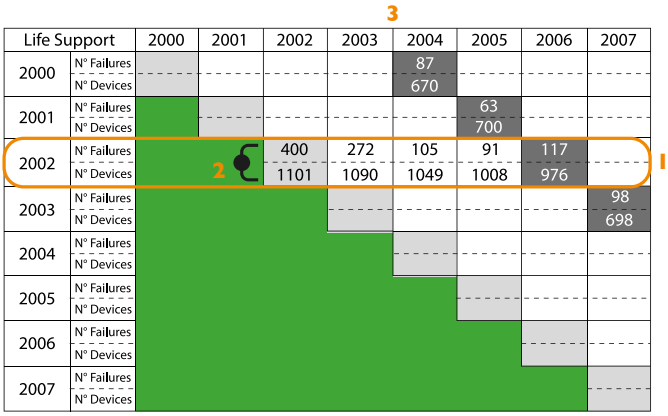
Figure 2. Classification of medical devices according to the Technological Complexity.



KPI Analysis

Finally, the last step of the methodology regards the use of three KPI applied to the previous devices categories:
(1) The Global Failure Rate (GFR);
(2) the Age Failure Rate (AFR);
(3) the Devices and Technologies Ratio (DTR).
These KPIs' aim is to objectively determine and study any typical skills for the previous medical devices categories.
The GFR is *"..the total number of failures - as measured by the total number of completed repair work order-divided by the total number of devices[7].."* It has been chosen because it measures reliability of medical equipment, which is fundamental in hospitals in order to guarantee continuity of medical services.
The AFR represents "the total number of failures divided by the total number of devices according to the years of use by users." It has been considered in the analysis because it provides further information with respect to GFR by taking into consideration usage aspects such as user experience, learning problems and ergonomics[8].
The AFR calculation follows the procedure reported as example in Figure 3 for Life Support devices. The first column represents the year of devices acquisition, with each row divided into two parts representing respectively the specific number of failures and the number of devices still in use at the subsequent years indicated by the other columns (point 1 in Figure 3). For instance, by considering the year 2002 as device acquisition year, the Failure Rate is calculated according to the changing number of devices in use and failures in the subsequent years (point 2 in Figure 3). It has been decided to only consider the devices in use each year, in order not to contaminate AFR values so as not to misinterpret a low AFR as a low number of failures.

Figure 3. AFR calculation procedure for Life Support devices.



Point 1: **Acquired devices at the year 2002**
1st row: n° of Failures at subsequent years;
2nd row: n° of Devices still in use at the subsequent years

Point 2:

0.4	0.25	0.1	0.09	0.09	0.08

Failure Rate Values for acquired devices at the 2002 at subsequent years.

Point 3: ∑ Failure Rate Values = 0.48
Point 3b: AFR_4 = 0.48 ÷ Years of Usage = (0.48 ÷ 4) = 0.12

Once the table is completed, by considering the fourth year of usage, the sum along the diagonals gives the sum of Failure Rate values after four years of use (point '3a' in Figure 3). By dividing this sum by the number of usage years considered, the mean AFR4 is obtained (point '3b' in Figure 3). The same procedure is followed for all the diagonals to obtain the complete AFR trend, from AFR1 to AFR7.
Finally the DTR is defined as the "number of devices" divided by the "number of different technologies". It has been considered because it is a simple and intuitive measure in analyzing the complexity of an environment by considering different technologies in use.

Results

The analysis has shown that:
• most of the technologies belong to the Medium category;
• the highest number of devices belongs to the Low-Technology class (almost 50% of all Hospital devices).
As shown in Figure 4, diagnostic and therapeutic areas are characteristic for High-Tech devices that are not present in Clinical Support activity. Most of these medical devices are installed in the diagnostic area, as is typical for Imaging. Limited-Tech characterizes both technologies and devices of Clinical Support activity. Non Limited-Tech equipment is typical for Life Support areas. Despite previous considerations, it is clear from analysis that Medium-Tech is the dominant technology in hospitals: first for number of technologies in Life Support, Laboratory and Therapeutic areas; second for number of technologies in the diagnostic area and first for number of devices (891 Medium-Tech versus 347 High-Tech device.
Further, the "acquisition trend" of medical devices has been obtained from the 'purchase contracts' according to the technology classes. Low-, Medium- and Limited-Tech present an acquisition peak every two years, High-Tech present a 5-year-period peak.

Figure 4. Technology distribution of medical devices according to their Destination of Use.

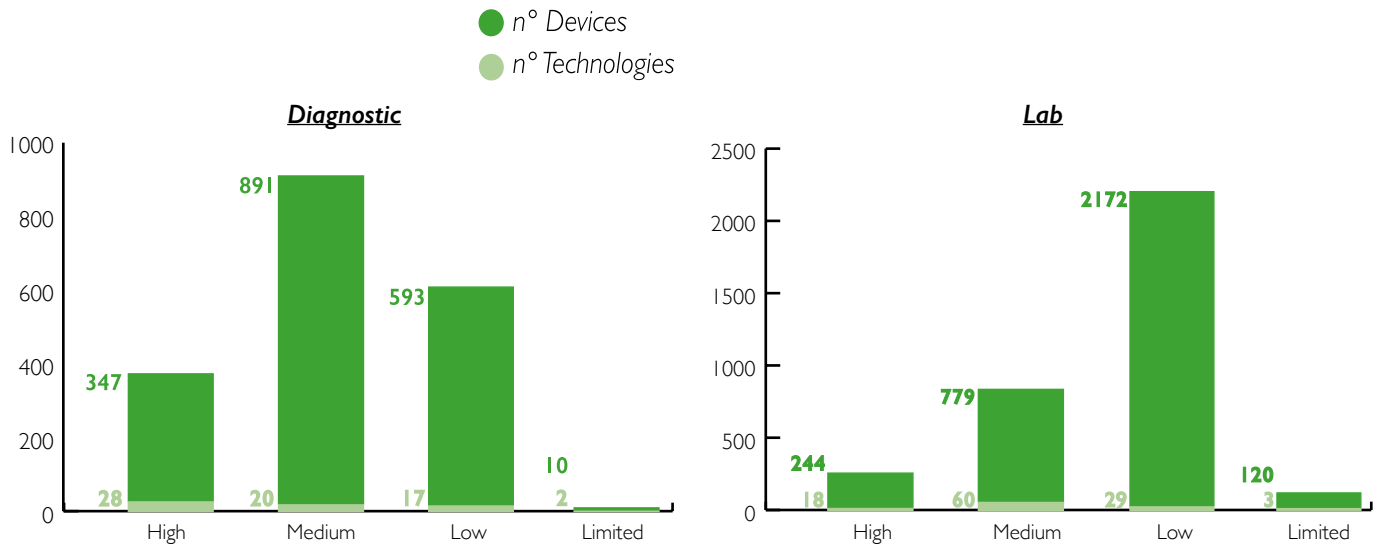
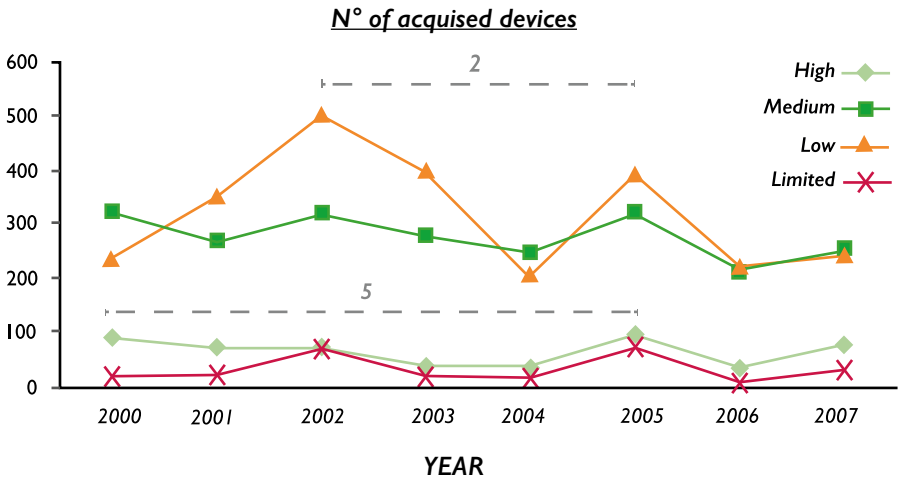


Figure 5. Medical Devices acquisition trends according to technology classes.

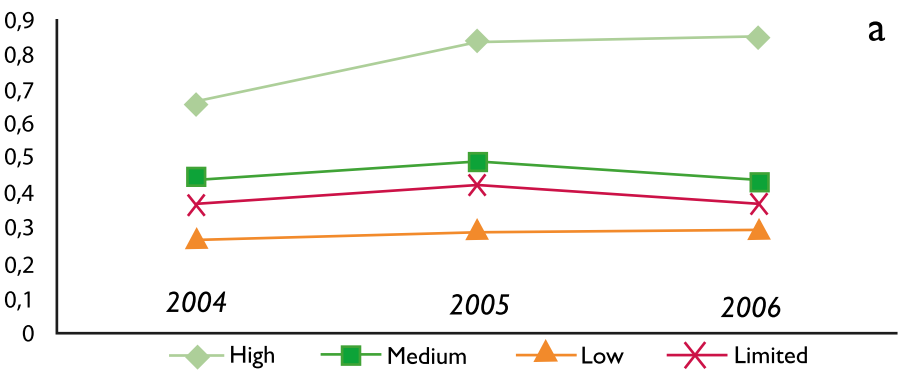


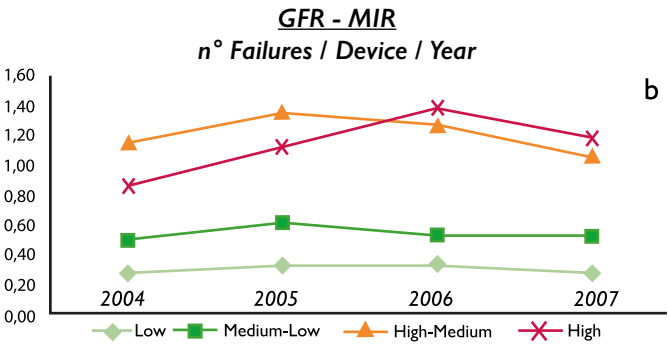
GFR analysis

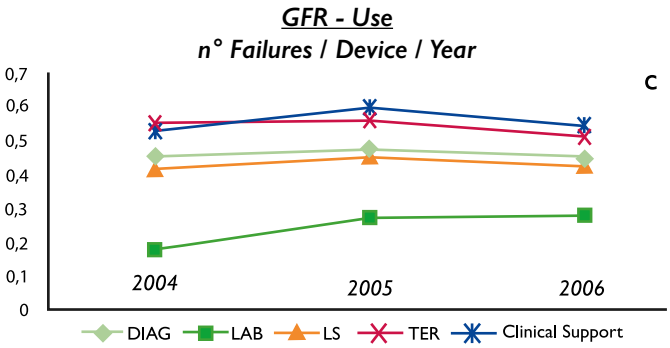
For the KPI analysis, GFR has been chosen for two main reasons: Firstly, it is interesting to evaluate possible relationships between failures trend and destinations of use. Secondly, GFR can help the Clinical Engineering Department to better understand causes of maintenance costs by analyzing if MIR depends on number of failures or if it depends on failure type.

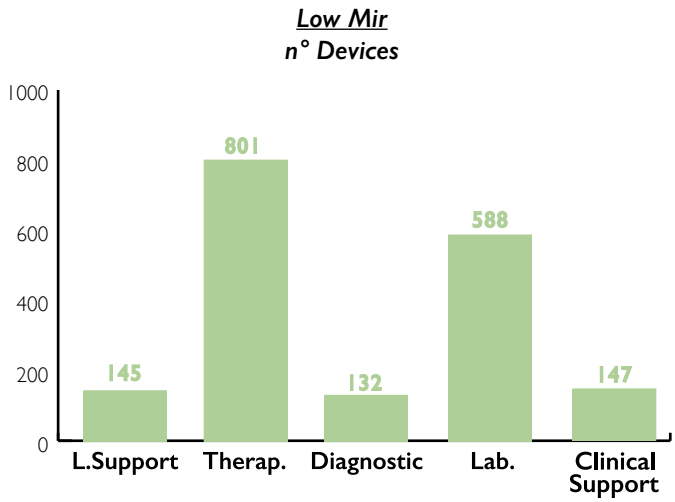
In Figure 6 the diagram 6a reports GFR related to technological complexity classification during three years (from 2004 to 2006). It includes all devices present in the hospital that year; new and old. The analysis has shown that the number of failures increases with technological complexity. High tech shows the highest GFR value, constant during the whole time. Medium-, Low- and Limited-Tech have a much lower GFR. Diagram 6b shows GFR applied to MIR categories. The graph points out High MIR results being proportional to number of failures. Indeed, the number of technical interventions is the critical point for high maintenance costs. Diagram 6c analyses GFR applied to destination of use classification. It is interesting to note how the laboratory is the area with the lowest GFR. Despite this, it contains the highest number of MIR devices (see Figure 7) and is second in terms of presence of High-Tech devices (I would expect high GFR at these conditions).

Figure 6. (a) GFR analysis applied to Technological Complexity; (b) GFR analysis applied to MIR; © GFR analysis applied to Destination of Use.







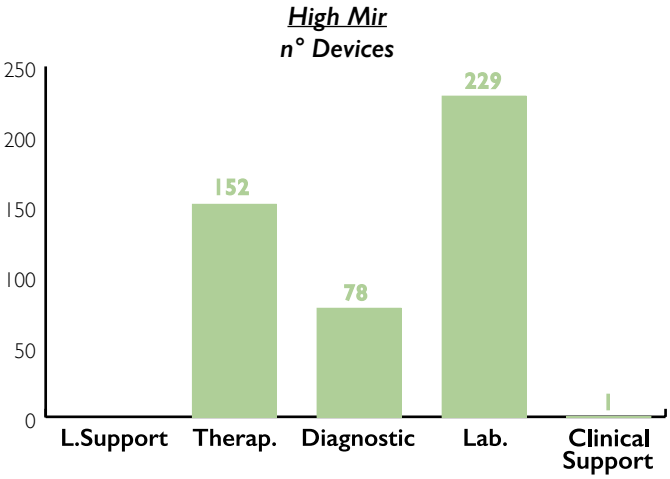


MIR classification

The results of MIR classification are reported in Figure 7. Most High MIR devices are used in the laboratory.There are no devices in Life Support areas and only one device belongs to Clinical Support use. For Low MIR equipment the majority is in Therapeutic areas, with 801 devices. Low MIR distribution includes all hospital destinations.

Indeed, it can be seen that the Laboratory is the highest MIR risk area in the hospital, with no particular risks in Life Support and Clinical Support areas, and it is second in terms of presence of High-Tech devices (I would expect high GFR at these conditions).

Figure 7. High and Low MIR distribution of medical devices according to their Destination of Use.



Two considerations:

1) The Laboratory is the most "technical" area with specialized technicians working there;

2) service contracts are well prepared in order to maintain High-Tech devices; attention to maintenance contractual services is considered much more here than in the other destinations of use.

On the other hand, therapeutic and Clinical Support have the highest GFR. The presence of many different technologies, especially for therapeutic areas (178 different technologies, Figure 1) means it is difficult to manage and use them. In addition, the presence of the patient leads users to consider patient's needs as priority over processes and protocols. Finally, Diagnostic and Life Support areas have similar values of GFR.

AFR index

The AFR index has been applied to the previous classifications and it has been analyzed for a period of seven years since the year 2001. It provides similar to GFR trends and is proportional to Technology level and Maintenance costs as well as GFR.

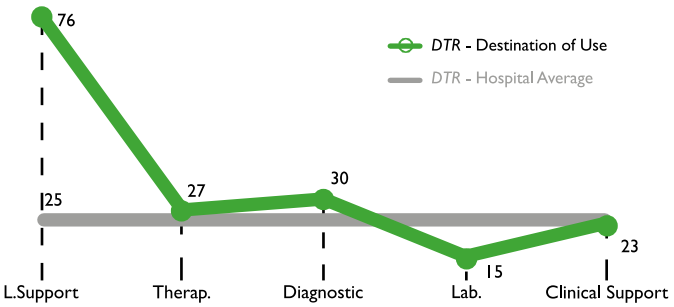
Furthermore, different areas in the hospital have the same AFR characterization met by GFR, see diagram 8c. The AFR decreases significantly during usage, and as it can be seen clearly in diagram 8a, AFR presents a strong decrease after the first year of its use in the hospital. Indeed, strong relations between learning, user experience and number of failures is demonstrated. High-Tech equipment is the most critical category. After the first year, AFR trend is constant and similar for all devices. In the first two years, vulnerability is an important aspect to consider during the acquisition phase and in learning/educational planning.

DTR indicator

The DTR indicator defined as "Number of Devices/ Number of Technologies Ratio" is an intuitive value, easy to calculate and helpful for easy and general considerations on technological characterization of medical areas. As Figure 9 shows, Laboratory and Clinical Support Activity are typical for low DTR. It signifies

a high presence of different technologies. On the other hand, Life Support presents a high DTR ('76' with respect to hospital average '25') indicating a low specialization in technology: low number of different technologies with respect to high number of devices. The necessity to dispose of back-up devices for this destination of use is satisfied by the high number of same technology devices used here.

Figure 9. DTR analysis applied to Destination of Use.



Conclusion

The proposed methodology has provided some useful KPIs for decision-makers to use for technical analysis in technology management such as acquisition, maintenance and technology replacement phases. The new index "AFR" is concluded to be an appropriate indicator for technical analysis on medical equipment, since it allows an health structures and technologies benchmarking. High AFR means high maintenance costs and High-Tech device management. Analysis has shown that usually, High-Tech devices are not as expensive for maintenance as Low- and Medium-Tech. This means good contract coverage for High-Tech and inadequate contracts for Low- and Medium-Tech equipment. More attention in the contractual phase, such as preventive maintenance plans[9] and full risk options requests for these categories would save money and improve health service in hospitals.

The use of the AFR index has further proved the importance of training courses for users, especially for High-Tech devices and for critical destination of use (e.g. Life Support Area).
Finally, the study of the acquisition trend of medical devices provides a further information for a long term equipment replacement planning in order to optimize resources. Further developments are connected to a technical dashboard development for a sustainable technology management in hospitals by including also usability and economic sections. This would help decision makers in technology replacement and management phase, allowing 'real time' and a 360 degree view of information on the technological situation in health structures.

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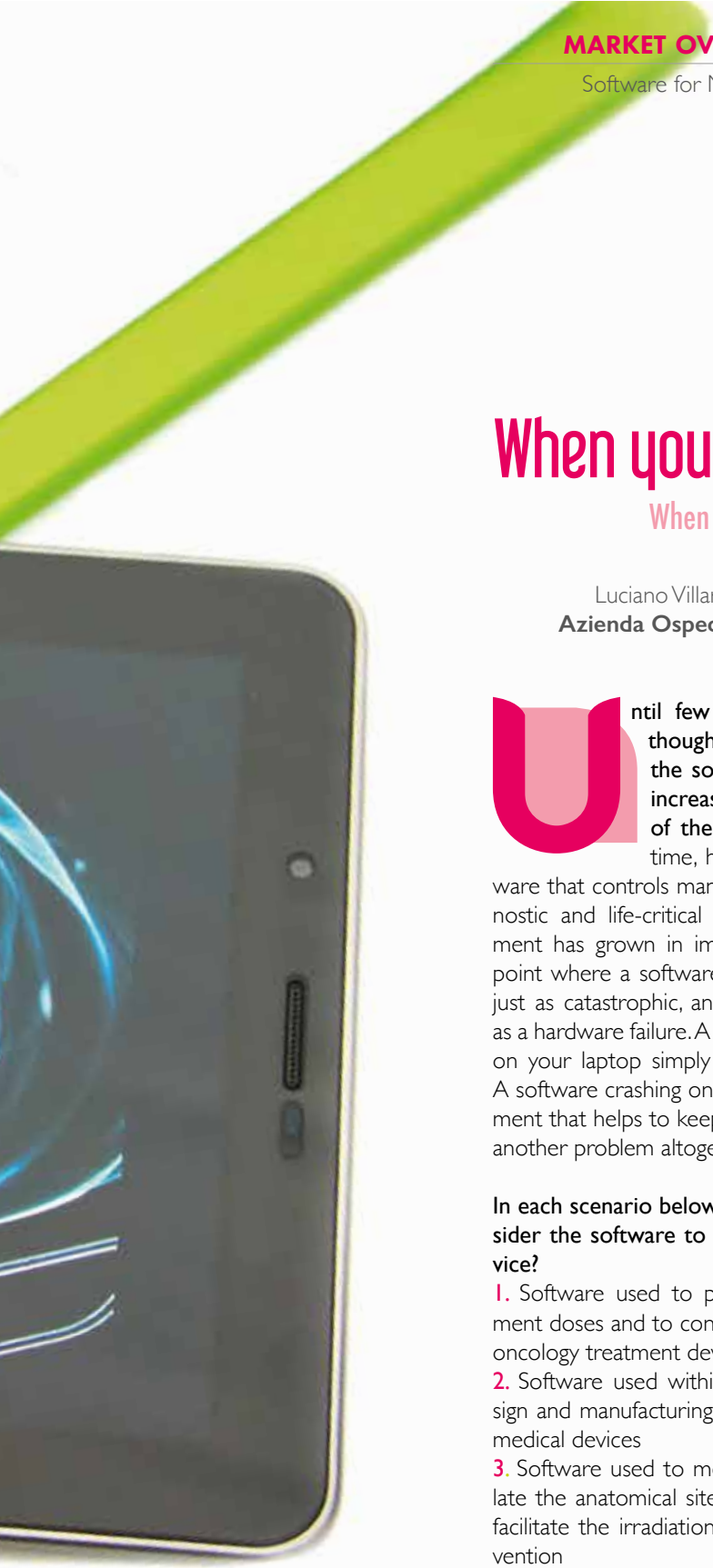
Photo

Software for medical devices.

Pelvis bone x-ray image show in tablet on medical chart

Praisaeng / shutterstock



When your life depends on software

When is software considered a medical device?

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Until few years ago, little thought was given to the software that is an increasingly crucial part of these devices. Over time, however, the software that controls many electronic diagnostic and life-critical electronic equipment has grown in importance, to the point where a software failure could be just as catastrophic, and life threatening, as a hardware failure. A software crashing on your laptop simply means a reboot. A software crashing on a piece of equipment that helps to keep a patient alive is another problem altogether.

In each scenario below, would you consider the software to be a medical device?

1. Software used to plan cancer treatment doses and to control the setting of oncology treatment devices
2. Software used within the overall design and manufacturing processes of the medical devices
3. Software used to measure and calculate the anatomical sites of the body to facilitate the irradiation of surgical intervention
4. Software embedded in an implanted pulse generator device
5. Software used to transmit administrative data such as a patient's name and address.

The answers to the examples above are yes, no, yes, yes and no, respectively.

This exercise highlights the increasing prevalence and complexity of software in the medical industry, but also underscores the difficulty of determining if the software is a medical device and what kind of classification rules apply under the European Medical Device Directive MDD 93/42/EEC, if it could be applicable.

Many critical functions performed by medical devices are directed by softwares, and because softwares are not a visible product, sometimes, we lose sight of its importance. In 2000, medical device software occupied national headlines when 28 Panamanian teletherapy patients received radiation overexposure: the Multidata Systems International Corporation Treatment Planning Software was implicated in 21 of those patients deaths.

This is an extreme example but it emphasizes both how pivotal softwares are to the function of some medical devices and the consequences of software's failure.

Software as a Medical Device Defined

So what is a software? An example provided by MEDDEV 2.4.1, Rev. 8, Guidelines on the Classification of Medical Devices for a Rule 12 device describes active medical devices as "intended for recording, processing or viewing of diagnostic images."

Guidance NB-MED 2.2, Rev. 4, Guidelines On The Qualification And Classification Of Stand Alone Software Used In Healthcare Within The Regulatory Framework Of Medical Devices:

1. Software intended for analysis of patient data generated by a medical device with a view to diagnosis and monitoring
2. Software intended for use by patients to diagnose or treat a physical or medical ailment (condition or disease)
3. Software that is a component and an integral part of a medical device

Operation of software requires electrical energy and software functions by converting this energy by means of interfaces and/or actuators, which are parts of the programmable electrical medical system."

These sentences contain a few key words. Point A refers to "diagnosis and monitoring" of patient data, which is why the fifth scenario of software described in the quiz is not considered a medical device. The software in the fifth scenario tracks administrative patient data. Point C is subject to some interpretation, but essentially, if the device cannot operate without your software, your software is "integral" and assumes the same classification as the device as discussed below. The software categories all diagnose, monitor, treat or alleviate disease. The software in the second scenario facilitates the manufacture of devices, but is not indicated for alleviate diseases.

What is the Classification for the Medical Device Software?

The MDD 93/42/EEC, Annex IX makes provisions for softwares that function as a medical device. Basically, it states that any software that drives a device or influences the use of a device falls automatically in the same classification.

Clearly, software may be viewed as a medical device or an accessory to a medical device or as a component and integral part of a medical device (automatically in the same class as the medical device and subject to the conformity assessment of the medical device).

The software's function guides the classification of the software medical devices. If the software is a medical device, it may be classified as Class I; however, if the medical device software is an integral component of a device as indicated above, it will assume the classification of the device. For example, a software that is part of a Class III medical device is considered as a Class III device.

Software is Considered as an Active Medical Device

This may be another concept that is difficult to reconcile and reasonably well explained by the NB-MED guidance, which states: "Operation of software requires electrical energy and software functions by converting this energy by means of interfaces and/or actuators, which are parts of the programmable electrical medical system." The NB-MED guidance document is interesting, because it attempts to delineate some of the inadequacies of the European regulations with regards to software. Fortunately, the proposed revisions to the Medical Device Directive and the Directive for Active Implantable Medical Devices (AIMD) attempt to resolve these omissions.

Photo
IEC 62304 imposes requirments on software for medical devices.
Patient in Intensive care unit of hospital.
nycshooter / istock

Softwares as Medical Devices with a Measuring Function

One last nuance that should be briefly discussed is the potential Class I medical device software may be subject to classification as a Class I medical device with a measuring function. And, if the software now is viewed as such, Notified Body involvement is required for CE Marking.

The Guidance MEDDEV 2.1.5, Medical Devices with a Measuring Function may be relevant to some softwares. Softwares with a measuring function must comply with a few characteristics: measure quantitatively a physiological function or anatomical parameter; measurement displayed in legal units or other acceptable units as described within European Directive 80/181/EEC; and the intended purpose implies accuracy, and failing to comply with the "measurement" could result in a significant adverse effect on the patient's health and safety.

To determine the proper European route to compliance for your software, consider the following questions:

- What is the intended use of the software?
- Does the intended use of the software designates it as a medical device? (The software provides instructions for an instrument for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease.)
- If yes, is the software considered as a component of a medical device? (The software drives or influences the use of the device.) If yes, the software assumes the class of the device.
- Is the software an independent device or accessory? If yes, does the software have a measuring function? If yes, perhaps the device is Class I measuring.

Revision of European MDD and AIMD

It is widely accepted that software is either a pivotal medical device or a component of a medical device. The revisions to the Medical Device Directive and AIMD reflect the issues regarding software and provide explicit references and clarifications.

In the revised Medical Device Directive, the preamble specifically describes software and acknowledges the "growing importance of software in the field of medical devices." It is proposed that software be referenced in the definition of the medical device and a statement included that software may be used with the medical device. The following sentence will be added to Annex IX: "Stand alone software is considered to be an active medical device."

In the AIMD, the Essential Requirement on software will be elaborated to discuss software validation and development lifecycle, risk management, validation and verification.

In the United States (US), starting three decades ago, the FDA increased its level of activity in reviewing the development of medical device software, due perhaps to coding errors causing patient overdoses in a radiation therapy device (Therac-25). An increased regulatory oversight of the FDA on medical device

Software manufacturers should implement the requirements in the beginning phases of new product development. This is critical. As the software industry has learned, the key to reliable software lies in the design and development phase. Unlike hardware products, it is virtually impossible to verify software after the fact.

software development processes and system testing has been described in safety research on infusion pump software.

In the US, the FDA has published a guidance (on the topic of medical devices) that specifically addresses medical device software.

In July 2011 the FDA published a guidance on medical mobile applications, with the final regulations issued on September 2013. These regulations only apply to "medical apps that transform a mobile device into a medical device or an accessory to a regulated medical device." Examples include apps that regulate an installed pacemaker or those that analyze images for cancerous lesions, X-rays and MRI, graphic data such as EEG waveforms, bedside monitors, urine analysers, glucometer, stethoscopes, spirometers, BMI calculators, heart rate monitors and body fat calculators.

Additional Considerations and Conclusions

Many ancillary topics also deserve mention. Conformity Assessment procedures require consideration of the development lifecycle; procedures for document control and configuration management and control of combinations between software versions and intended hardware. The published software medical device standards (not an exhaustive list) include IEC 62304 (2006), Medical Device Software-Software Life Cycle Processes, ISO/IEC 90003 (2004) and IEC 60601 series.

Software is a component of many complicated medical devices or is an independent medical device or accessory, and as such, it is important for manufacturers to appreciate that their software may require CE Marking.

Software manufacturers should implement these requirements in the beginning phases of new product development. This is critical. As the software industry has learned, the key to reliable software lies in the design and development phase. Unlike hardware products, it is virtually impossible to verify software after the fact.

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Photo
Software for medical devices.
Software may be viewed as a medical device or an accessory to a medical device or as a component and integral part of a medical device
istock

Oral-B® Unveils New App Technology At Mobile World Congress 2015

CINCINNATI, March 2, 2015 /PRNewswire/

Oral-B, the worldwide leader in oral care, unveils improvements to its App at the 2015 annual GSMA Mobile World Congress meeting in Barcelona, Spain. The App connects the user to its highest performing toothbrushes, by creating seamless brushing routines and allowing expanded professional guidance. Oral-B continues to innovate and personalize the Oral-B App (which is already changing oral care behaviours when used with the Bluetooth-connected toothbrush) with the creation of Dental Care Journeys and Professional Guidance. Additionally, Oral-B is proud to announce the opening, in October 2015, of the Oral-B App's Application Programming Interface (API) and Software Development Kit (SDK), which will enable users to become a part of the increasingly connected oral care digital experience by working with third parties.

Since the SmartSeries and Oral-B App's debut at Mobile World Congress last year, initial results indicate improved worldwide oral care behaviours in a number of important measures. The App data shows that Oral-B electric toothbrush users are now brushing on average 2:24 minutes, compared to the less than 60 seconds average of the manual toothbrush users. Additionally, over half of these recorded brushing sessions included flossing, rinsing, and tongue cleaning. Through a combination of these statistics and consumer feedbacks, Oral-B can deduce that with real-time feedback, users are encouraged to brush longer, with less force and more in-line with their dental professionals' recommendations.

Oral Care Statistics from Oral-B SmartSeries and App Use:

A total of 83% of brushing sessions are over two minutes, with a global average brushing duration of 2:24.
The Oral-B App has been downloaded nearly 300,000 times since its launch; there were 87% active users in the month of December 2014. Approximately 60% of brushing sessions are leveraging the rinsing, flossing and tongue cleaning App reminders, for a more holistic oral care routine.
The Oral-B SmartSeries with the Oral-B App has helped users achieve accurate brushing across all quadrants and areas of the mouth.

"We are encouraged by the consumer feedback and data regarding our App's ability to improve and maintain oral care routines and have used this proof as inspiration to continue investing and innovating in this area,"said Stephen Squire, Global Brand Director, P&G. "In partnership with dental professionals and consumers, Oral-B has created the next generation brushing experience that utilizes personal goals, unique dental considerations and entertainment to ensure that our consumers are getting the best possible results outside a dentist chair."

After a year of collaborating with consumers and dental professionals to enhance the App, Oral-B has addressed the need for a more personalized brushing experience. Oral-B users can now select journeys to fit their oral care goals and their dental professional can provide direct recommendations and feedback within the App. The goal for these improvements is to ensure that a user can comply with their dental professionals' recommendations between office visits through a streamlined App experience.

Dental Care Journeys:

Each personalized Dental Care Journey is tailor-made to help users' achieve their oral care goals, including whiter teeth for an upcoming wedding, or fresh breath for food lovers.
The Journeys deliver a more active and engaged brushing routine for a pre-designated period of time, and also offer recommendations for corresponding products to match each Journey.
Users can select among five Journeys: Fresh Breath, Plaque Fighter, Whitening, Gum Health or Ortho Care.

Professional Guidance:

A dental professional can add extra brushing time of order to focus on certain areas in the mouth, select dental conditions and provide specific brushing and interdental cleaning instructions for his/her patient to follow at home.
A dental professional can provide product recommendations via the App, selecting products based on their patients' specific needs.
Patients can share their compliance statistics with their hygienist and dentist via e-mail, as a way to track and discuss areas to improve, and help advance their oral care routines.
Beginning in late 2015, the App will allow users to voluntarily integrate their oral care information into other digital programs by opening the API. This will create a seamless venue for users to holistically monitor their well-being, and could potentially provide an opportunity for users to be rewarded for good brushing behaviour through various reward programs. Oral-B is working to enable developers to create or extend apps with a user's brushing data. If interested, please email Oral-B at sdk@oralb.com.

SOURCE Oral-B

Heraeus enters agreement to acquire NeoMetrics

ST. PAUL, Minn. and PLYMOUTH, Minn., March 18, 2015 /PRNewswire/

Heraeus Medical Components, a global business unit of Heraeus Holding GmbH, has executed a share purchase agreement to acquire 100% of the stock in NeoMetrics. NeoMetrics, headquartered in Plymouth, Minnesota, specializes in designing and manufacturing guidewires and components for medical devices. The company's production facilities, in both Minnesota and Costa Rica, include cleanroom manufacturing and extensive guidewire fabrication technologies. The closing of this transaction is expected to occur in the next 60 days.

"With this acquisition, **Heraeus Medical Components** will add new interventional technologies to increase their leadership position as a sourcing solution for the world's medical device companies. "We are excited about the potential growth opportunities within the interventional field," said Dr. Nicolas Guggenheim, President of Heraeus Medical Components. "NeoMetrics' experience in the development of interventional and vascular access guidewires, substantially increase upon our existing component capabilities. We plan to use our combined expertise to bring new solutions for our medical device customers."

"We are excited to become part of Heraeus Medical Components," said Dave Liebl, President, of NeoMetrics. "Joining Heraeus will allow us to support our continued growth, including the opportunity to introduce our products and expertise to new markets. Both companies share a culture of consistently exceeding customer expectations."

The management team and employees of NeoMetrics will continue as part of Heraeus, contributing important domain expertise and ensuring continuity for customers. Gene Champeau, co-founder and CEO of NeoMetrics will assist Heraeus in developing new business platforms and product strategies on a consulting basis. Heraeus intends to continue operation of both of the NeoMetrics facilities post-closing.

About NeoMetrics

NeoMetrics, headquartered in Plymouth, Minnesota, is a private company that was founded in 2001. The company operates exclusively as an OEM partner of medical device companies.

They are specialized in designing, manufacturing and securing Regulatory clearance for interventional and vascular access guidewires.

About Heraeus

Heraeus Medical Components is a global business unit of Heraeus Holding GmbH.

Heraeus, the technology group headquartered in Hanau, Germany, is a global private company with more than 160 years of tradition. They create high value solutions for our customers, strengthening their competitiveness for the long term. Their fields of competence include precious metals, materials and technologies, sensors, biomaterials and medical products, quartz glass, and specialty light sources.

In fiscal year 2013, Heraeus achieved product revenue of €3.6 billion and precious metals trading revenue of €13.5 billion. With some 12,500 employees in over 110 subsidiaries worldwide, Heraeus holds a leading position in its global markets.

SOURCE Heraeus Medical Components

Nanotechnology in Medical Devices Market Forecasts Research To 2019 by Product, Application and Regions

DALLAS, March 23, 2015 /PRNewswire/

Global Nanotechnology in Medical Devices Market was valued around $5 Billion in 2014 and expected to reach around $8.5 Billion by 2019 with a CAGR of around 11-12% during the forecast period 2014 - 2019 - **Says a New Research Available at RnRMarketResearch.com**

Over the last five years, the nanotechnology-based medical devices market witnessed tremendous growth. This was due to the growth in the aging population and to government support.

Naturally, with the growth in the nanotechnology R&D expenditure, even international research collaborations increased . Complete report on **Nanotechnology in Medical Devices Market by Product (Biochip, Implant Materials, Medical Textiles, Wound Dressing, Cardiac Rhythm Management Devices, Hearing Aid), Application (Therapeutic, Diagnostic, Research) - Global Forecast to 2019** available at http://www.rnrmarketresearch.com/.

In this report, the global nanotechnology-based medical devices market is segmented on the basis of products and applications. On basis products, the nanotechnology-based medical devices market is categorized into biochips, implantable materials, medical textile and wound dressing, active implantable devices, and others. The implantable materials segment is divided into dental filling materials and bone restorative materials; instead, the active implantable devices segment is divided into cardiac rhythm management devices, hearing aid devices, and retinal implants.

On the basis of applications, the nanotechnology-based medical devices market is segmented into therapeutics applications, diagnostics applications, and research applications.

The global nanotechnology-based medical devices market is dominated by six players that accounted for around 65-70% of the global market in 2014. The major players in the global nanotechnology-based medical devices market are Stryker Corporation (U.S.), 3M Company (U.S.), St. Jude Medical, Inc. (U.S.), Affymetrix, Inc. (U.S.), PerkinElmer, Inc. (U.S.), Starkey Hearing Technologies (U.S.), and Smith & Nephew plc (U.K.).

Active implantable devices accounted for a major share of the nanotechnology-based medical devices market. The nanotechnology-based medical devices market for active implantable devices is primarily driven by the growing incidence of age-related disorders such as hearing and cardiovascular dysfunctions. In addition, the growing awareness about these diseases and increased acceptance of the hearing aid devices are further driving the market for active implantable devices.

In 2013, North America accounted for the largest share to the global **nanotechnology in medical devices market,** followed by Europe, Asia-Pacific, and RoW. However, Asia-Pacific is expected to be the fastest-growing region during the forecast period owing to the rapidly aging population, rising adoption of advanced nanotechnology-based medical devices, the increasing accessibility to healthcare facilities, and rising R&D and healthcare expenditure.

The global nanotechnology-based medical devices market is expected to grow at a significant CAGR of around 11-12% during the forecast period (2014-2019). The market is mainly driven by the growth in aging population, rising adoption of nanotechnology-based medical devices, and increased nanotechnology R&D expenditure. In addition, the governments of several nations are investing heavily in developing and commercializing new nanotechnology products.

However, safety issues regarding nanotechnology-based medical devices, severe regulatory guidelines, and time-consuming approval processes for these devices are hampering the growth of this market to a certain extent.

SOURCE RnR Market Research

KIMES 2015

KIMES 2015 At a Glance

31st Korea International Medical & Hospital Equipment Show (KIMES 2015) *"The Health of Today, The Happiness of Tomorrow"*

1) The Blueprint for the Future of Medical Centric event, KIMES
KIMES 2015, paid attention to attendees by various events set up by the organiser and maximised the effect of the exhibition. Majority of the exhibitors obtained positive and great responses from qualified visitors at KIMES 2015. Exhibitors have reported that market is subsisting and forging forward still, alongside rapid growth of Korea medical industry, exhibitors and visitors felt that businesses were strongly connected in the KIMES.

2) The Latest Medical Equipment introduced by the Leading Global Names The largest trade fair which filled 38,350 sqm of exhibition presented with a wide range of products by 530 Korea manufacturers, USA 117, Japan 67, Germany 96, China 137 and with the other international manufacturers. The show was highlighted the increasingly important role played by domestic companies, Samsung, Listem, JW Choongwae, DK Medical, BIT Computer, Alpinion. In addition, the world leading brands, GE, Fuji, Shimadzu, Hitachi fuelled the event to be the attraction market in Asia.

3) Appointed as a Top Leading Exhibition in Korea Ministry of Trade, Industry and Energy selected KIMES 2015 as a Korea Top Leading Exhibition in great supports to recruit new customers and to reinforce medical business from Korea to the world.

Also, Korean government appointed medical industry as the one of the leading industry that propelled Korean economy in the future, and the government provided blueprint of financial and political backing for the industry.

4) In-depth Seminars with Variety Topics 139 sessions of seminars were concurrently held in COEX Conference Center during the KIMES to deliver quality information and knowledge. Covered topics in the KIMES conferences were from government policies on medical devices market, newest technologies on medical devices to financial technology for the doctors.

5) Medical Device Component Pavilion.
As the growth of interest in medical device, KIMES organized the Medical Device Component Pavilion in Hall A to increase the interest on components manufacturing companies as well as expanding the exhibits categories in KIMES.

6) KIMES Scholarship Contribution
Wishing to contribute to the health care industry through finding talented student and to foster the upcoming generations, we started to offer "KIMES Scholarships" to young students whose college major is in biomedical engineering from 2014.

7) KIMES offered exhibitors the perfect tool to exposure on media. All exhibitors were given the chance to exposure their profile marketing through our media partners and benefited with the spotlight in the medical industry. It helped to reach a unique audience of new customers and reinforce their existing business relationships.

http://kimes.kr/eng/

Cosmofarma 2015

Cosmofarma Exhibition, the European leading event for the Pharmacy world, organized by BolognaFiere Group with the prestigious partnership of Federfarma and Cosmetica Italia (Gruppo Cosmetici in Farmacia), closed its 19th edition with 29,771 visitors (+8% compared to the 2014 edition), with a strong increase of attendees from abroad. (+21%).

The brands exhibiting were 910 (320 from the pharmaceutical sector, 290 from the cosmetics sector and 300 from the sector focused on the services for the pharmacy).

80 conferences, workshops and meetings (including 5 ECM courses) underlined the important role Cosmofarma plays in the professional and scientific education. They are a specific feature of an event calling to all the professional figures of the pharmacy world, offering solutions to address industry, services and new regulations in the changing scenarios that characterize our age. This topic was discussed during the meetings held by Federfarma, Farmindustria, Utifar, Fenagifar, Asis, AIIPA, Federsalus, Sunifar, with the support of numerous organizations including IMS Health, Doxa Pharma, DE International, Institute of Health Sciences. For the first time, Cosmofarma organized "DermoCosm – Vita Cutis", the first Congress under the chairmanship of Professor Antonino Di Pietro with the accession of all nine dermatological and aesthetic associations, with the purpose of relate ever closer two professionals, physicians and pharmacists. Cosmofarma also hosted the traditional focus on nutrition and nutraceuticals, with numerous initiatives organized by Professor Enrico Roda.

www.cosmofarma.com

Regulatory updates:

SCENIHR releases Final Opinion on the use of Nanomaterials & Bisphenol A in Medical Devices

Abstract from European Commission Enews

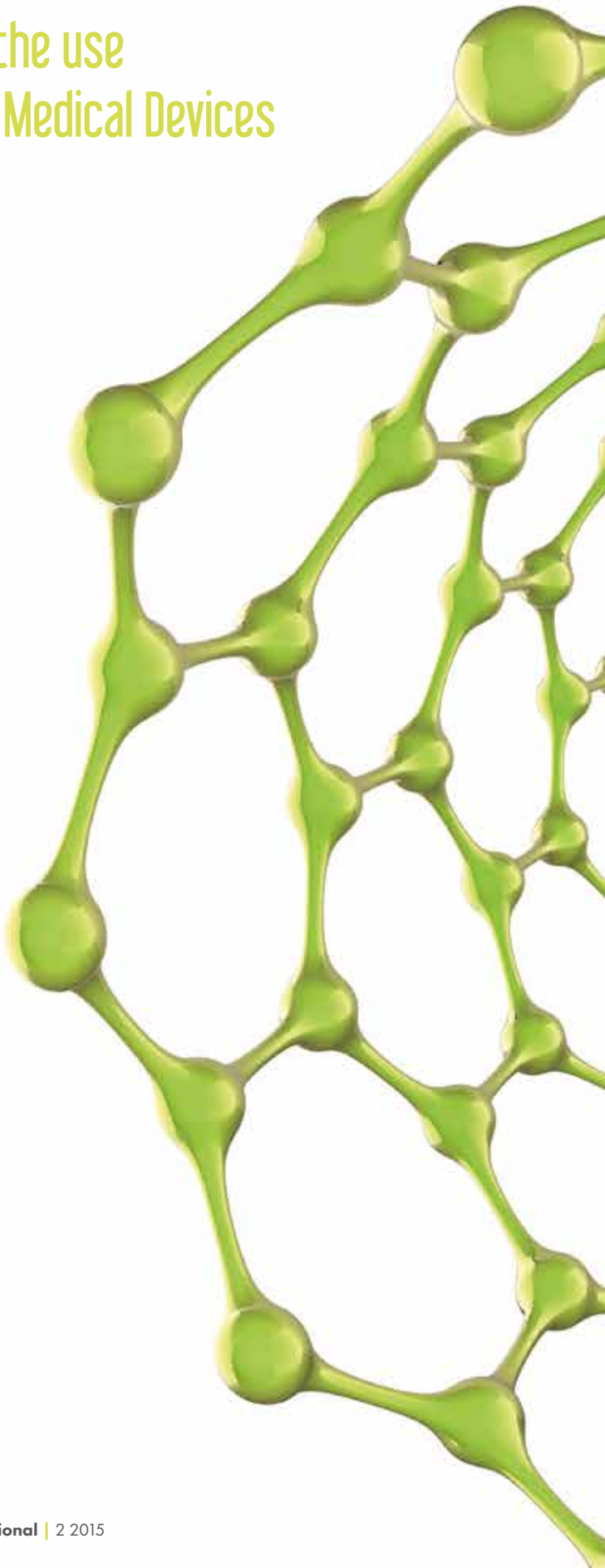
Nanotechnologies make use of very small objects or artefacts. Nanomaterials are an increasingly important product of nanotechnologies. They contain nanoparticles, smaller than 100 nanometres in at least one dimension.

Nanomaterials are coming into use in healthcare, electronics, cosmetics and other areas. Their physical and chemical properties often differ from those of bulk materials, so they call for specialised risk assessment. This needs to cover health risks to workers and consumers, and potential risks to the environment.

This is currently done on a case by case basis, but risk assessment methods need to be kept up to date as the use of nanomaterials expands, especially as they find their way into consumer products.

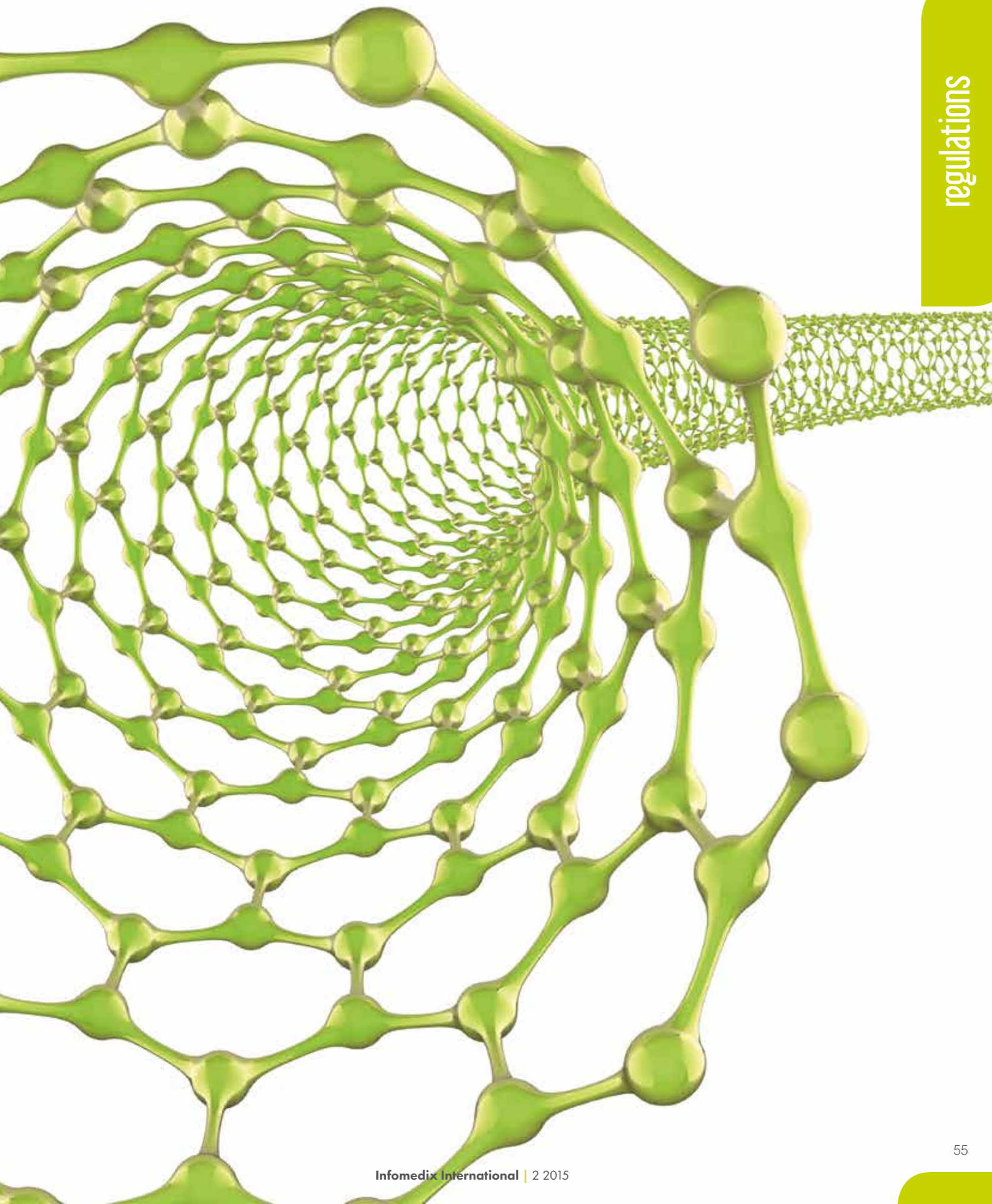
What do we know about the possible health risks of exposure to nanomaterials, and how can assessment of these risks be improved?

(SCENIHR)



On January 13th, 2015 SCENIHR issued a 'Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices'. The opinion addresses the use of nanomaterials in medical devices and to provide information for risk assessors regarding specific aspects that need to be considered in the safety evaluation of nanomaterials.

A public consultation on this opinion was opened on the web-site of the non-food scientific committees from 18 July 2014 to 3 October 2014. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.



What are nanomaterials?

Nanotechnologies involve designing and producing objects or structures at a very small scale, on the level of 100 nanometres (100 millionth of a millimetre) or less. Nanomaterials are one of the main products of nanotechnologies – as nano-scale particles, tubes, rods, or fibres. Nanoparticles are normally defined as being smaller than 100 nanometres in at least one dimension.

As nanotechnology develops, nanomaterials are finding uses in healthcare, electronics, cosmetics, textiles, information technology and environmental protection.

The properties of nanomaterials are not always well-characterised, and they call for risk assessment of possible exposures arising during their manufacture and use.

Eleven organisations and companies participated in the public consultation providing input to the main scientific questions. In total 110 contributions were received and considered by the SCENIHR and the Working Group and the scientific opinion has been revised to take account of relevant comments.

The SCENIHR Opinion is considered as a guide that explains how to evaluate the risk when a nanomaterial is used in a medical device. This Guide addresses the use of nanomaterials in medical devices and provides information for risk assessors regarding specific aspects that need to be considered in the safety evaluation of nanomaterials. According to the EU Recommendation for the definition of a nanomaterial (Commission Recommendation 2011/696/EU, EC 2011) any particulate substance with at least one dimension in the size range between 1 and 100 nm is considered a nanomaterial.

The Guidance provides information to assist with safety evaluation and risk assessment on the use of nanomaterials in medical devices that should be considered in conjunction with the ISO 10993-1:2009 standard. The Guidance highlights the need for special considerations in relation to the safety evaluation of nanomaterials, in any possible distinct properties, interactions, and/or effects that may differ from conventional forms of the same materials.

The SCENIHR recommends a phased approach for evaluating the risk of the use of nanomaterials in medical devices based on potential release and characteristics of the nanomaterials to avoid unnecessary testing. The phases cover particle release (phase 1), particle distribution and persistence (phase 2), hazard assessment (toxicological evaluations) (phase 3), risk characterisation/risk assessment (phase 4). In phase 1 an evaluation of the potential for the device to release nanoparticles either directly or due to wear of the device during use should be carried out.

In phase 2 the aim is to determine the distribution of the particles released and also their persistence potential. In phase 3 the hazard is assessed using appropriate toxicity tests taking account of the exposure characteristics and potential for persistence in specific organs. This will provide input for the final risk characterisation (phase 4).

The estimated risk needs to be compared to the risk from the use of comparable devices not incorporating nanomaterials in judging the acceptability of the risk.

The SCENIHR concludes that the potential risk from the use of nanomaterials in medical devices is mainly associated with the possibility for release of free nanoparticles from the device and the duration of exposure.

Moreover, on February 27th the SCENIHR also published the final opinion on "The safety of the use of bisphenol A in medical devices". Concerning the safety of vulnerable groups such as infants, pregnant and breast-feeding women when exposed to bisphenol A (BPA) through medical devices have recently been raised. Such medical devices, include implants, catheters, and many dental devices.

The final opinion aims to assess whether OR NOT the use of bisphenol A in these devices could give reasons for safety concerns, to provide indications on limit values for BPA release from medical devices and to identify any patient group, e.g. infants, pregnant and breastfeeding women who would be particularly at risk.

When drafting the final opinion the SCENIHR considered the temporary oral TDI (t-TDI) of 4 µg/kg b.w./day derived by EFSA as a solid base for carrying out the risk assessment for the use of BPA in medical devices. Several exposure scenarios have been evaluated taking into account the material used, the information related to BPA leaching, the duration of a single treatment and the frequency of treatments, giving rise to toxicologically relevant acute, short and long term exposure. However, the information available is very limited and in many cases due to the lack of experimental data, only estimations were used.

Concerning exposure via the oral route, it can be concluded that the long term exposure to BPA via dental material is far below the recently derived t-TDI and poses negligible risk for human health associated to BPA exposure.
Some risk for adverse effects may exist, when the BPA is directly available for systemic exposure after non-oral exposure routes, especially for neonates in intensive care units, for infants undergoing prolonged medical procedures and for dialysis patients.

In spite of this, it should be considered also the benefit of medical devices: the survival of neonates, for example, often depends on the availability of the medical devices which causes a relatively high BPA exposure. The possibility to replace BPA in these products should be considered against their efficiency in the treatment, as well as the toxicological profile of the alternative materials, when available.

However, better data on exposure would be beneficial for the refinement of the present risk assessment, to be carried out when new data on exposure via medical devices will be available.

With reference to the Final Opinion, the Polycarbonate/Bisphenol A Group and the Epoxy Resin Committee of PlasticsEurope, the Association of European Plastic Manufacturers, comment as follows on the SCENIHR opinion on the safety of the use of BPA in medical devices:
Since 2012, SCENIHR had evaluated the safety of the use of BPA in medical devices.

In its final opinion published at the end of February, SCENIHR confirmed the safety for many medical applications based on BPA. SCENIHR found out that available exposure data from medical devices is very limited.

As a consequence of consistently using conservative worst case assumptions for exposure to account for the lack of data, and relating uncertainties, SCENIHR considers there may be a risk related to some parenteral exposure scenarios for certain medical devices, namely neonates in intensive care, infants under prolonged medical procedures, and dialysis patients.

However, the Committee underlines that such potential risk has to be seen in context of the essential benefits that these devices provide for the therapy of the patients. SCENIHR cautioned not to rush to potential alternative materials: these must be evaluated in terms of 'efficiency in the treatment, as well as the toxicological profile of the alternative materials.'

According to SCENIHR, there is currently not enough data available for this evaluation.

The PC/BPA group understands the need for more specific data on exposure from medical devices in their specific use patterns, in order to allow for a more robust identification of the respective safety margin. This would allow for a more substantiated derivation of potential risks.

The PC/BPA group will further evaluate available relevant data related to polycarbonate products and would welcome engagement from the other medical devices industry partners in order to reduce the data gap in this area.

"The long track record of proven life-saving benefits from polycarbonate medical devices coupled with the margin of safety demonstrated by SCENIHR's evaluation should give confidence to patients and medical professionals in the continued use of these products." says Jasmin Bird of the PlasticsEurope Polycarbonate/Bisphenol A industry group.

Sources:
European Commission
(Directorate General for Health and Food Safety) -
http://ec.europa.eu/health/press_material/index_en.htm

Henry Schein Donates Health Care Products to Help Ongoing Relief Efforts for Victims of Malawi Flooding

MELVILLE, N.Y., March 26, 2015 /PRNewswire/

Henry Schein, Inc. (NASDAQ: HSIC), the world's largest health care products and services provider to office-based dental, animal health and medical practitioners, has donated essential health care products to its NGO (non-governmental organization) partner Direct Relief. These health care products will help the victims of the devastating floods in Malawi, a natural disaster that, according to Direct Relief, has taken the lives of more than 176 people and left an estimated quarter of a million people displaced.

This initiative is part of Henry Schein Cares, the worldwide Company's social responsibility program. In order to help in the immediate response for emergencies around the world, Henry Schein Cares partners with international relief organizations sending them, on a regularly basis, health care products to store in their warehouses and to use as soon as the disasters occur.

"Coordination of relief efforts in areas affected by disasters is essential, and we applaud the work of Direct Relief, which is working with local organizations on the ground in Malawi to ensure that the health care supplies we donate, are being used effectively and efficiently," said Stanley M. Bergman, Chairman of the Board and Chief Executive Officer of Henry Schein, Inc.

"Henry Schein's work to help the people of Malawi is part of our ongoing commitment to give back to society. A commitment that has marked our Company for more than eight decades.

As we have grown into a multinational corporation, the scope of this responsibility has grown proportionately."

Henry Schein Cares "helps health happen" by expanding access to health care for at-risk populations through the support of communities and no-profit organizations dedicated on increasing preventive care, treatment, and health education. In addition to enhancing emergency readiness and relief, Henry Schein Cares support activities focused on increasing wellness and building up knowledge about the delivery of health care services.

"Thanks to the donations from Henry Schein Cares, Direct Relief was able to rapidly respond with a shipment to Kasungu District Hospital in the central, rural region of Malawi," said Jessica Koval, Direct Relief's International Program manager. "The supplies will allow the hospital to continue on providing health care services in a time when resources are stretched thin and the number of patients due to the flooding is increasing".

About Henry Schein Cares

Henry Schein Cares stands on four pillars: pushing Team Schein Members to reach their potential, ensuring accountability by extending ethical business practices to all levels within Henry Schein, promoting environmental sustainability, and expanding access to health care for underprivileged people and at-risk communities around the world. Health care activities supported by Henry Schein Cares focus on three main areas: increasing wellness, developing capacity in the delivery of health care services, and assisting in emergency readiness and relief.

Firmly rooted in a deep commitment to social responsibility and in the concept of enlightened self-interest championed by Benjamin Franklin, the philosophy behind Henry Schein Cares is a vision of "Doing well by Doing good." Through the work of Henry Schein Cares to enhance access to health care for those in need, the Company believes that it is furthering its long-term success.

"Helping Health Happen Blog" is a platform where health care professionals can share their volunteer experiences on delivering assistance to those in need across the globe.

To read more about how Henry Schein Cares is making a difference, please visit: www.helpinghealthhappen.org.

Photo
Families wait in line for access to basic health services at the Sekeni II camp for people displaced by the flooding
Source: UNICEF

Unitaid against Tuberculosis

Drug resistant strains of tuberculosis, which are hard to detect and treat, killed an estimated 210,000 people in 2013 and now threaten to infect and kill millions more unless improved diagnostics and shorter treatments become widely available.

Every year all forms of tuberculosis (TB) kill more than 1.5 million people and at least 3 million new TB cases go undiagnosed.

As countries around the world mark World TB Day under the theme "Reach the 3 million", UNITAID and its partners are underscoring their efforts to promote use of new diagnostic techniques and drugs that will make it possible to more than halve treatment times for MDR-TB, a disease which infected an estimated 480,000 people in 2013.

A report by the United Kingdom's All Party Parliamentary Group on Global TB, published today, has warned that up to 75 million people could lose their lives to multi drug-resistant TB (MDR-TB) over the next 35 years if the world fails to tackle drug resistance.

The parliamentary report said that treatment for drug resistant TB is so "complex, expensive and toxic" that less than half of people successfully complete treatment. If treatment courses for MDR-TB were shorter and less arduous, more patients would complete treatment and fewer cases of resistance would develop, the report noted.

UNITAID is now investing $60 million with Partners in Health, Medicins Sans Frontieres and Interactive Research and Development to make new, more effective medicines available and improve patients' chances of being cured from 48% to 70%, and drive a sharp fall in new infections.

Up to 50 different MDR-TB medicine combinations are in use globally, usually involving a gruelling two-year course of multiple pills daily and injections with harmful side effects such as deafness. The new drugs have the potential to make it possible to treat the disease in less than nine months and to eliminate the need for injections.

The spread of drug-resistant TB strains has been fuelled by patients receiving intermittent medication or failing to complete treatment. Rising numbers of patients are also now contracting MDR-TB from people with a drug-resistant strain of the disease.

Over the next four years, 2,600 patients will be enrolled on treatment with the new TB drugs in 17* countries through the UNITAID investment. A more user-friendly and effective treatment regimen will also be devised following a clinical trial with 600 patients.

"UNITAID's investment will help make MDR-TB treatment more effective and easier-to-bear, thereby helping patients to be better treated and to halt the disease's spread" said Lelio Marmora, Executive Director UNITAID. "This new investment is part of our broader TB portfolio that is introducing innovations for a more effective global response to the disease."

He said new medicines to treat drug resistant TB were urgently needed, in part due to the three-fold increase in new cases diagnosed since 2009.
UNITAID has also been investing to expand use of up new state-of-the-art diagnostic technologies such as GeneXpert®, which can shorten the time to diagnose drug resistant forms of TB from weeks to only a matter of hours.

**Peru, Lesotho, Kazakhstan, Ethiopia, Kenya, Georgia, Armenia, Kyrgyzstan, Swaziland, India, Myanmar, Belarus, Pakistan, Indonesia, Bangladesh, DPRK, and Nepal*

Photo
Pulmonary Tuberculosis
istockphoto / stockdevil

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• 13-15/05/2015

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• 15-18/05/2015

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• 19-22/05/2015

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(Sao Paulo, Brazil)

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June

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• 04-06/06/2015

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Venue: Hilton Beirut Habtoor Grand Hotel , Beirut - Lebanon

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•10-11/06/2015

Medtec France

(Besançon, France)

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July

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• 31/07 - 02/08/2015

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Venue: Chennai Trade Centre
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August

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• 05-07/08/2015

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(Miami Beach, FL - USA)

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