67. e-Health – Ambient Assisted Living and Personal Health Systems

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This chapter focuses on the healthcare aspects of ambient assisted living (AAL) and the contributions that personal health systems (PHS) may bring. As part of these categories, this chapter examines the areas of self-management, tele-assistance, media and multimedia solutions, fall detection, robotics, bio-parameter monitoring, auto adaptive treatment systems, tele-therapy, tele-consultation, tele-surgical assistance, and smart homes. For each approach, the nature and purposes of the technologies will be examined and examples will be discussed. The chapter will subsequently address the benefits and the challenges ahead for AAL and PHS technologies within the broader context of e-Health. Finally, the chapter concludes with observations and trends.

Advances in information and computer technology (ICT) over the last half-century have led to many innovations crucial for the delivery of healthcare, including the emergence of e-Health. Within the context of e-Health, this chapter examines the contribution of ICTs to the fields of ambient assisted living (AAL) and personal health systems (PHS). Albeit in different manners, both AAL and PHS include products, processes, or services that can contribute to maintaining individuals within their home environment, while providing them with the support necessary in light of their conditions or pathologies. This chapter examines the areas of self-management, teleassistance, media and multimedia solutions, fall detection, robotics, bio-parameters monitoring, auto adaptive treatment systems, teletherapy, teleconsultation, telesurgical assistance, and smart homes. For each area, the nature of the technology, the purposes for which it may be used, as well as examples of developments are outlined. Technological developments occur within a social, societal, ethical, economic, and global context. This chapter examines the benefits of these technological developments and the challenges ahead for their development, adoption, and widespread use. It concludes with some observations and proposes some trends for future developments.

Health and healthcare systems are the product of a convergence of biomedical, social, technological, economic, ethical and political factors. The delivery of effective, safe and efficient healthcare services and products to patients is a challenge facing governments around the world. The nature and scope of this challenge has become more pressing over recent decades as the global population has grown and will continue to grow, as life expectancy has increased and will continue to increase, as the burden of disease has become better understood and has shifted, and as the costs of healthcare systems and services have become unmanageable in their current state.

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67.1 Background

Many healthcare systems were developed during periods where the population they served was smaller and were designed in accordance with that population. In 1960, the world population was under three billion. As of 30 March 2010, the United Nations estimated the human population of the world to have been 6 800 000 000 in 2009 [67.1].

In light of these developments, the current healthcare system model is not sustainable for much longer. The 1980s policies of cost containment are arriving at their limits (wage control and price controls plus investments postponement) [67.2]. To maintain an equivalent healthcare level and availability, the health-related expenditure would need to increase at a constant rate to cope with the geographical and nongeographical changes. As Fig. 67.1 shows, the total costs and expenditures on health have continuously increased during recent decades. Unfortunately, this increase in expenditures has not resulted in improved services. For example, extensive waiting times face patients in hospitals, in emergency rooms, and when seeing a specialist. In Canada, for instance, a recent study found that the total waiting time between referral from a general practitioner and treatment, averaged across all 12 specialties and 10 provinces surveyed, was 16.1 weeks in 2009 [67.4].

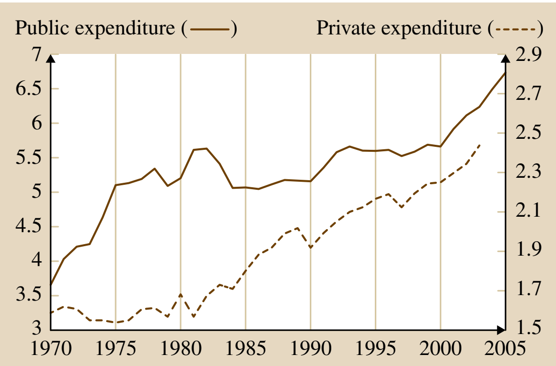

Fig. 67.1 Evolution of public and private OECD total health spending [67.1] as a percentage of GDP (after [67.2])

Moreover, other trends make the current models of healthcare systems unsustainable. The increasingly ageing population is also an important contributor to this nonsustainability. As Fig. 67.2 illustrates, by 2050 there will be significantly larger portions of the population who will be older than 65 years of age. Asia, Japan in particular, and Europe are the two regions where a significant number of countries face severe population ageing in the near future. In these regions, within 20 years many countries will face a situation where the largest population cohort will be those over 65 and the average age will be approaching 50.

This ageing of the population will result in many societal benefits. This demographical evolution also needs to inform the adaption of healthcare systems and services in order to offer effective, safe, and efficient healthcare services. As Fig. 67.3 shows, currently the

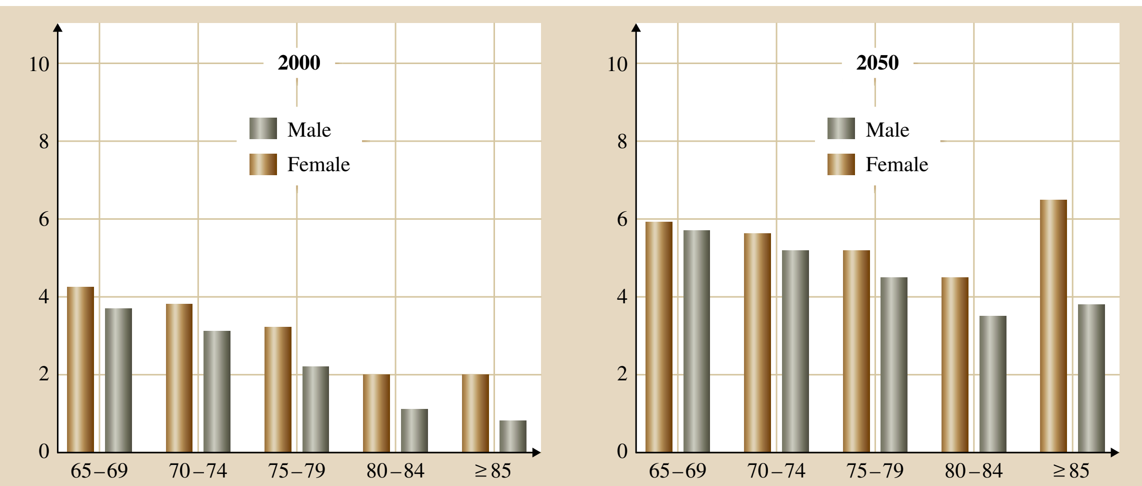

Fig. 67.2 Aging Forecast for OECD countries (after [67.3])

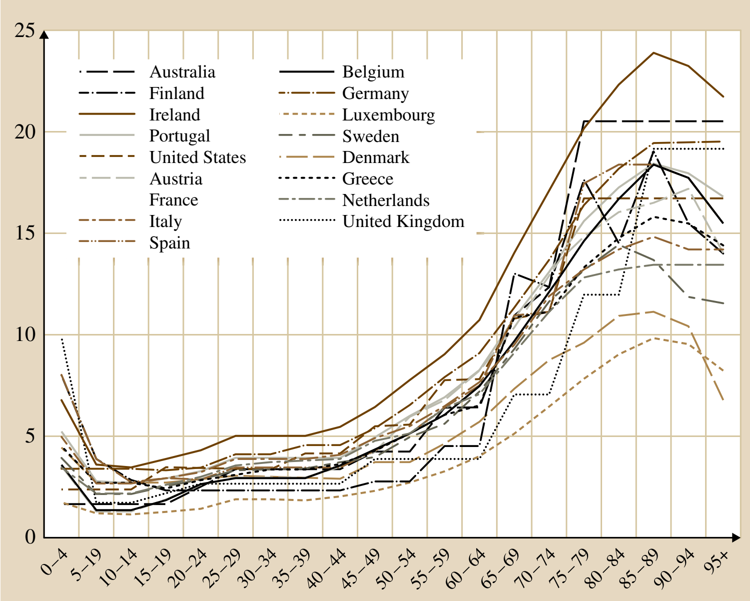

Fig. 67.3 Public healthcare expenditure by age groups as a percentage of gross domestic product (GDP) (after [67.2])

peak of the costs for healthcare services is for the portion of the population aged 75 years and older. The precariousness of the current system is compounded by the converse demographic phenomenon of the shrinking number of working adults. Currently, in Europe, there are 4 adults working to sustain each person aged over 65 years. However, by 2050, this number will decrease and there will be only 2 adults working to sustain each person aged over 65 years [67.5].

Another trend that is significantly impacting healthcare systems is the increased burden of chronic diseases. Chronic diseases are diseases of long duration and generally slow progression. Chronic diseases, such as heart disease, stroke, cancer, chronic respiratory diseases, and diabetes, are by far the leading cause of mortality in the world, representing 60% of all deaths [67.6]. In regards to those living with chronic disease, the statistics are also daunting. 860 million people worldwide suffer from one or more chronic condition. As of 2000, for example, 45% of Americans had at least one, and 23% had two or more chronic conditions. In Europe, chronic conditions account for up to 86% of all deaths.

67.1.1 e-Health

While no tool, process, or technology will address the multitude of issues currently facing healthcare systems, numerous phenomena are emerging that can contribute to finding better and different solutions. One such field is that of e-Health. e-Health can be described as an overarching term used to describe the application of information and communications technologies in the health sector. It encompasses a whole range of purposes from purely administrative through to healthcare delivery. While there is no globally-agreed upon definition or categorization of e-Health, Fig. 67.4 presents a categorization of e-Health that has been developed and used within the European Communities.

This chapter will focus on the areas of e-Health referred to as ambient assisted living (AAL) and personal health systems (PHS). The European Framework Programmes have focused considerable attention on and have set aside considerable investment for the areas of ambient assisted living and personal health systems. The Framework Programmes (FP) are programs of the European Union with the mission of funding and encouraging research and applications around the EU's key research areas. The term *personal health systems* was introduced in the 1990s (and first introduced in the Fifth Framework Programme, FP5-1998), while the term *ambient assisted living* was first widely used in 2000. Although they sometimes use different nomenclature, other economies are also allocating considerable resources in the areas of AAL and PHS.

Broadly defined, AAL is the use of information and communication technologies (ICT) in a person's daily living and working environment to enable individuals

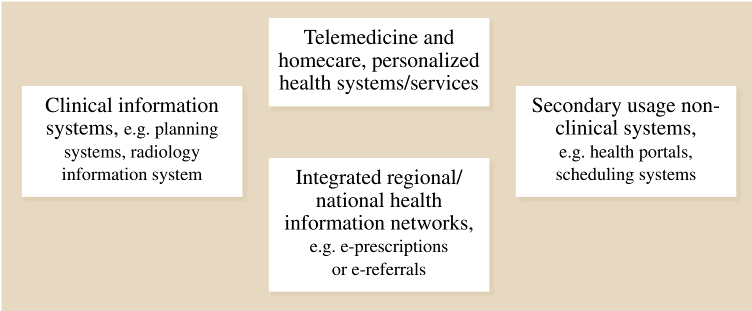

Fig. 67.4 The four components of e-Health [67.8]

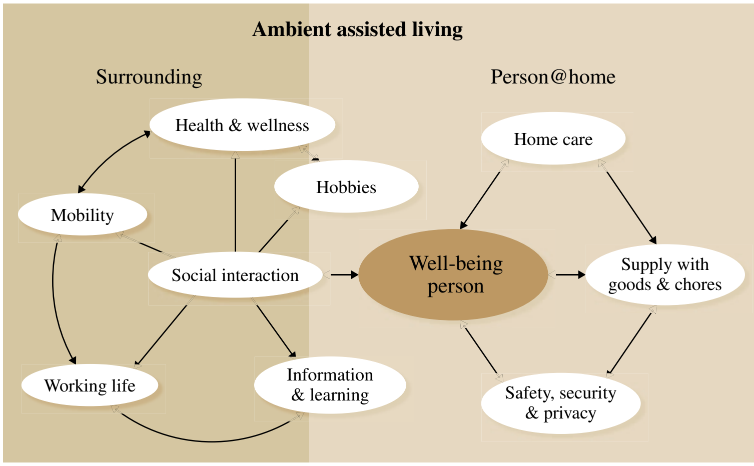

Fig. 67.5 Ambient assisted living application environments [67.9]

to stay active longer, remain socially connected, and live independently [67.7]. As Fig. 67.5 illustrates, AAL adopts a holistic and person-centric approach to ensuring the well-being of the individual. In order to achieve this objective, AAL aims to address more than healthcare aspects. As such, AAL covers many aspects such as mobility, social interaction, hobbies, chores, etc.

From a healthcare perspective, AAL includes any product, process or service that can help directly or indirectly to maintain individuals within their home environment, while providing them with the support necessary in light of their conditions or pathologies. AAL solutions aim to stabilize or even increase the autonomy of the individuals, facilitate medical treatments, and monitoring from home, and/or ease the carrying out of day-to-day tasks. AAL solutions are based on the desire of individuals to remain within their home environments as long as possible and to delay their entrance into institutionalized environments. These approaches provide solutions for the elderly, for incapacitated individuals, individuals recovering from a condition, surgery or a disease, or for individuals with cognitive, motor, or neurological needs.

Personal health systems may be considered to include wearable and/or fixed/portable systems, based on advanced sensors, microsystems, and telemedicine services for personal health monitoring [67.10, 11]. Some of the objectives that have been attributed to PHS include [67.12]:

- Detection of early signs of health status decline
- Notification of critical conditions to health professionals
- Improvement the sense of union within the family by sharing health information
- Identification of the interdependency between a person's health and their lifestyle
- Offering healthcare to remote, rural or doctor-deprived areas
- Bringing healthcare to developing countries
- Providing real-time multisourced reliable physiological data to health professionals.

The pressing need to develop and diffuse PHS technologies is their contribution to prevention, detection, diagnosis, monitoring and surveillance. For example, the European Heart Network reports that in Europe four million individuals die from cardiac diseases [67.13]. With portable heart monitoring systems capable of automatically alerting a healthcare centre capable of immediate response many lives could be saved.

67.2 AAL and PHS Approaches

This section will explore different PHS and AAL approaches. PHS or AAL approaches will generally contain one or more of the following components:

1. Data collection: The element is in charge of collecting the image, video, sound, text, or measurement of interest. The gathering may be automatic (e.g. use sensors) or manual. For example, the patient may enter text information. The PHS may be devices that are *wearable*, such as a portable heart rate chest belt, while AAL tools may be portable or fixed within their environment, such as a webcam.
2. Short-term memory: The element is responsible for ensuring the short-term storage of the data collected. There is a trend for memory chips to increase in capacity and to in reduce size and price. For example, memory cards can currently measure approximately 1.5 cm^2 and can reach 32 GB [67.14].
3. Local visualization: The element will allow the patient to visualize the fixed or continuous data collected.
4. Communication network: The element will move the data from the location of the patient to a remote location, where the server(s) is (are) located. There will generally be three parts: a transmitter (TX), the network itself, and the receiver (RX).
5. Database(s): The element will archive the information. This information can be fixed (such as patient ID or age), or incremental such as the data collected. Another type of information that is sometimes used is event tracking, such as user logins to the system (when a user accessed the system).
6. Analysis: The element will examine the data collected and the patient information to select a result and/or an action.
7. Action launcher: The element will launch an action following the analysis. The typical actions would be a flag in the database, a transmission of an SMS or email, and a local or deported sound or light alert.
8. Visualization: The element will allow the health professional, the helper, and sometimes the patient, to visualize the data collected, the patient information, the analysis rules and outcome, and the action initiated.

While not all PHS or AAL approaches will contain all of the components mentioned above, the indispensable component will be the data collection. Figure 67.6

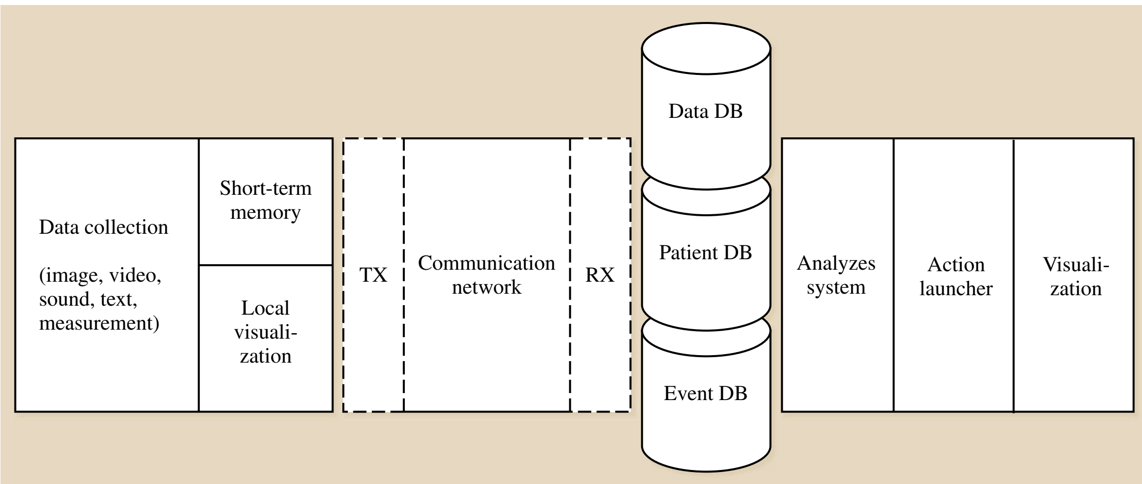

Fig. 67.6 Components of AAL and PHS

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presents a visual image of the components of PHS and AAL approaches. In such approaches, the components that are not present as often include the automatic analysis and action launcher.

PHS and AAL approaches can contribute throughout the healthcare delivery process. Moreover, they can intervene in more than one stage of the healthcare delivery process. These solutions may contribute in the prevention, diagnostic, monitoring/surveillance, and treatment/therapy stages.

67.2.1 Self-Management

Self-management tools are devices, instruments, or web sites, normally available to a large number of people, that assist individuals, and sometimes their natural helpers, in healthcare prevention and monitoring.

Health Portals (Prevention – Diagnostics – Monitoring – Treatment)

Description. A health-related portal is a web site that would present information that is perceived by the person to be useful to his or her health prevention or surveillance. There is a large variety of websites, with different levels of information or service quality. Behind the websites will be government agencies, private or public hospitals, universities and research units, associations, companies, patients etc.

The health portals normally have one of the following objectives:

- Information – To facilitate the access to drug, diagnostic, or treatment information; healthcare providers, processes, comparisons; provide patient, helper of GP's testimony.
- Coaching – With some basic input information from the user, to define some risks or recommendations; track measurements.
- Exchange and community creation/reinforcement – To provide a platform where patients and their helpers can exchange on real-time or deported.
- Archiving – To provide a storage space for the person to keep health-related data.
- Reminders – To enable the person or his/her helper to plan reminders such as medication or appointments. In this case, the reminder can be directed to an email, a SMS, or a landline phone.
- Healthcare products – To facilitate the ordering and purchase of drugs or medical equipment.
- Health institution or insurance account management – To facilitate the management and understanding of the person's account situation for his or her insurance or any other organization involved in the healthcare process.

North America is the most developed region, with a strong patient/consumer demand and usage. The European Union has established guidelines for quality healthcare related websites, i. e. transparency, authority, honesty, privacy and data protection, regular information updating, accountability, responsible partnering, editorial policy, and accessibility [67.15].

Certain countries have established a certification to validate the quality of health-related websites; for example, since 2004 the Haute Autorité de Santé (HAS) in France has had the mission to deliver these certificates. This French Agency used the HONcode certification (established by the Health On the Net Foundation, Switzerland) to validate the website. However, there is no correlation between certificated sites and usage; the most-used sites are the ones that are better *referenced* in web search engines, independently of the certifications [67.16].

Examples. In 2007 Microsoft and Google entered the field with the Microsoft HealthVault and Google-Health. The features of each system are listed in Table 67.1.

At the end of 2008 and the beginning 2009, the company User Centric evaluated the feedback from 30 end-users and concluded that Google-Health was more user-friendly (navigation and data-entry) [67.17]. However, certain features such as device data collection is under development with Google Health but already available in HealthVault. The latter is more focused on B-to-B partnerships. For the moment, both services are available only in North America, but in some European countries they will be launched in 2010–2011.

Reminders (Prevention – Treatment)

Description. The outcome of a treatment will depend on the correctness of the diagnosis, the accuracy of the prescription, and finally on the proper follow up of the treatment. The patient's involvement remains very limited in the first two steps; however, the treatment is mostly his or her responsibility. The World Health Organization calculated that only half of the patients with long-term therapies followed their prescriptions correctly [67.18]. Reminders are a simple way to reduce some of the nonadherence.

Another area where reminders are important are at the beginning of neuro-degenerative diseases. Re-

Table 67.1 Comparisons between HealthVault and Google-Health

	HealthVault	Google Health
Collect health information	Manually/import	Manually/import
Archive health information	×	×
Share health records	×	×
Search health information – web	Directly/indirectly	Directly/indirectly
Search health information – associations	Indirectly	Indirectly
Push health information/health authorities	×	×
Enter medications/prescriptions	Manually/import	Manually/import
Purchase your medication	Indirectly	Indirectly
Obtain personalized coaching	Indirectly	Indirectly
Obtain drug interactions		×
Enter test results	Manually/import	Manually/import
Agenda	Indirectly	Indirectly
Reminders	Indirectly	Indirectly
Import files and images	Manually/import	Manually/import
Find a doctor	Indirectly	×
Import data from medical devices	×	
Enter weight manually	×	
Note: The features were not tested, but are declarative		

minders can be useful to organize certain tasks, for example, a vocal or image reminder when it is lunch time. Unfortunately, when the disease is more advanced, reminders are not effective. Reminders can be web services that trigger an SMS, video, voice phone call, or LED; they can also be portable devices that read out a recorded or default message.

Examples. There are systems that do not require an additional device but would use the existing communication material of the user (e.g. fixed line phone, mobile, or email). The reminders can be planned in advance and delivered vocally by a call center [67.19] or delivered automatically using a synthetic voice, an SMS, or an email after scheduling from a web application [67.20].

There are other solutions that would require the acquisition of a specific-purpose device. Examples of portable reminder devices are: a watch showing the item to remember in its display (e.g. cadex watch), a pillbox that beeps and vibrates when it is time for a medication (e-pill), and a device that plays out the recorded message at specified time (e.g. memotext).

Heart Rate Monitoring (Prevention – Diagnostics – Monitoring – Treatment)

Description. A heart rate device is a portable system used to measure the heart rate (normally heartbeats per minute, or bpm). It can be visible and transmitted in real-time, or archived and transmitted once connected to a PC or communication gateway. Even though there are around ten body parts where the heart rate can be measured easily, for portability reasons most of the available devices use electrodes attached to a chest strap.

The important technical and commercial development of heart rate monitoring portable devices was done by sportsmen and women who used the measurements to improve their training. However, heart rate monitoring can be used for patients to leverage efforts, to alert in the case of a possible risky situation, or to understand the pattern during a timeframe (a day, a week, ...). It consists of a chest or finger band with an electrode strap and a connector; this band sends the heart rate information to a receiver, normally a watch or a mobile phone (Fig. 67.7). The information can be stocked in the device to be downloaded at a later stage into a PC (it can be downloaded using a cabled or a wireless solution). Once archived in the local PC or a remote server, a more detailed analysis can be performed manually or automatically. Newer models may include an accelerometer, which can help to calculate the distance completed and the mean/maximum speed of the journey.

Examples. The market leader is Polar, with a heart rate measurement using a chest strap. The reception/local archiving and visualization is done through a watch. While most other vendors follow this model for their so-

Fig. 67.7 Example of a finger heart rate measurement (after [67.21])

lutions, there are some that use different measurement points, such as the index. Personal heart rate monitors are priced from 50 to 900 USD.

Activity Monitors (Prevention)

In order to monitor the activity performed in a timeframe (a day, a week), there are activity monitoring devices that track the number of steps done, the calories burned, and the total mileage. An example is the clip by fitbit (launched at end of 2009). It has a USB connector to transmit data to a central server, which then prepares and presents the information on a webpage [67.21]. The

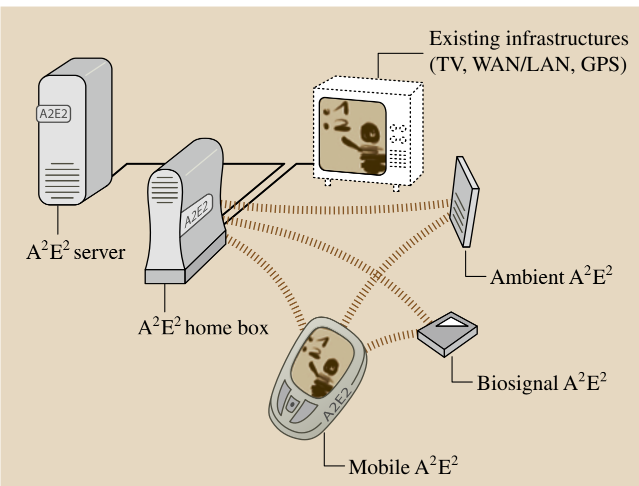

Fig. 67.9 The EU funded project A_2E_2

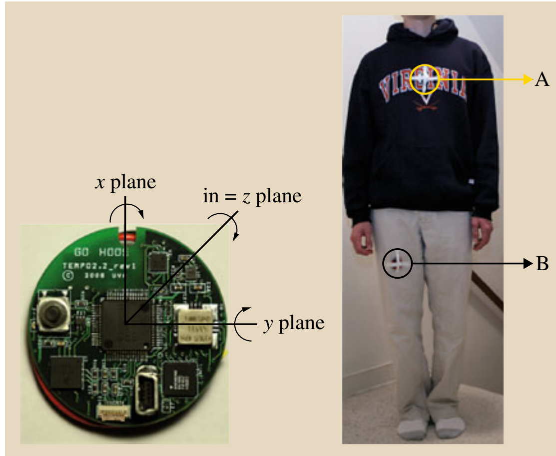

Fig. 67.8 Example of clip activity monitor (after [67.22])

webpage has some analysis capabilities. A competing solution tracks and provides more information to the user by using an armband with added sensors (temperature, accelerometer, and heat flux). The product is commercialized by Bodymedia [67.23].

Motivational Exercising System (Prevention – Monitoring)

Tracking activity or calories burned can sometimes be enough motivation to regularly exercise; however, consumers above 75 years old are not the main customers of activity monitoring systems, and the benefits that can be gained from regular exercise are considerable.

The objective of an EU funded project (A2E2, Fig. 67.9) is to build a system that will induce elderly people to exercise regularly. It tracks the activity performed with ambient and personal sensors; based on the personal profile and the data of those sensors the system will then establish an adapted communication. It consists of a user interface (TV or mobile), a collection and communication system, biosensors, ambient sensors, with the archiving and analysis capabilities in a server [67.24].

Teleassistance (Monitoring)

Description. Teleassistance or home assistance is a service that consists in providing the possibility for the user to reach a person with the appropriate capacities to answer a request or to treat an emergency situation. The National Emergency phone numbers (i. e. 911 in the US and Canada, 112 in Europe) are the most widely used teleassistance service. In the 1970s, associations and companies started to propose a private or associative service that linked the customer to a call centre. It was intended to deal with isolation and emergency. The emergency is usually just a situation definition and a bridge to the National Emergency teams; there are few cases where a medical presence is available 24/7 to perform a first remote diagnostic.

Teleassistance is the most extended commercial AAL offer. In 2008 for example, there were 1.5 million subscriptions in the UK, 600 000 in Spain, and 350 000 in France (as stated by the president of the French Association of Teleassistance Companies, AFRATA, Claude Mordelet [67.25]). The variation is linear to the financial engagement of the public sector (subsidies).

Traditionally, teleassistance is limited to a home support using a communication device connected to the fixed line, with a reach of around 100 m using a portable pendant or bracelet (with a red button to declare an alert). Pushing a button sends an alert to the screen of the call center who will call back the user; the communication device answers automatically in loud-speakers. The new generation of services expands the offering from the following perspectives:

- Service (keep a double of the house key, order a taxi, do a hairdresser appointment, provide the weather forecast...).
- Intelligence (activity detection, GPS, recorded reminders...).
- Mobility (medium or long-range alert and communication...).
- Environment coverage (include fire detection, window or door breaking detection...).

Consequently, assistance and monitoring start to overlap, and this trend will continue in the coming years. An area where commercial remote assistance is just starting is the monitoring and control of medical equipment such as pumps and prostheses.

The typical system components are:

- The alert system – normally portable devices such as the bracelet or pendant, but they can also be fixed, for example a button fixed to the wall of the restrooms
- The communication gateway – which will receive the local alarm and send it to the remote server
- Storage and presentation – the alerts are stored in a database and presented to the appropriate teams for action.

In the case of a mobile alert system, the first two components can be combined in the same device.

Examples. Examples of new generation services include home safety services, which include environment monitoring, and are widely proposed by the West Lothian County [67.26]. Another example available in France is témo [67.27], which uses a mobile alert and communication system with GPS. One of the largest players, Tunstall, started offering environment monitored assistance in addition to the traditional assistance plus some basic telemonitoring services. In Bologna, Italy, a project run by the Department of the INAIL Prosthesis Centre in Vigorso di Budrio provides a good example of remote assistance to tune medical devices based on patient-located data. The project consists in remotely analyzing and controlling an upper-limb prosthesis via a microprocessor controlled arm (MCA) [67.28].

Media and Multimedia Solutions (Prevention – Diagnostics – Monitoring – Treatment)

Description. Images, audio, and videos can be exchanged in real-time or deferred time; the exchange can be patient to health professional(s), health professional to health professional(s), and patient to patient(s). The approach of sharing audio/video/image in healthcare is useful for second opinion processes, better monitoring (e.g. regular wound evolution follow-up), diagnosis (e.g. detailed images for dermatology problems), or even improve treatments (e.g. identify secondary effects that the patient is not aware of, or does not think important to share).

When the video is real-time, it is referred to as videoconference or videoteleconference (VTC). In order to make the exchange operational, it is necessary to have a large bandwidth, otherwise the images would freeze and the sound would not be synchronized to the image. The minimum recommended bandwidth is 384 kbits/s. When there is a high bandwidth, the screen(s) quality is high and the screen(s) size sufficiently large to allow showing the persons and objects in their real size, the term telepresence is used.

Image and audio sharing is more accessible than videoconferences, since it does not require such an important bandwidth, and digital cameras or microphone are accessible to a larger portion of the population in Western countries, with a trend to having a phone equipped with a digital camera, which allows a real-time dispatch from practically anywhere. The quality of the camera or image will depend on the requirement; however, a 10 mega pixels digital camera can be easily found at less than 100 USD, which would have an

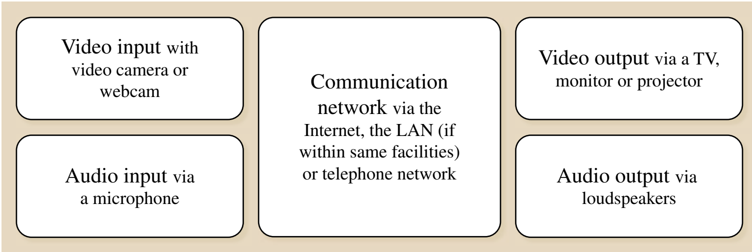

Fig. 67.10 Components of a VTC solution

enough quality for most of the applications. The components of a VTC solution are shown in Fig. 67.10. Image sharing will replace video input/output by an image input, while the audio solution will not have the video input/output.

Examples. In Sherbrooke, Canada, a new service was implemented in 2010, named TASP or *téléassistance en soins de plaies*. At the patient's home, a visiting nurse will film a wound and in parallel, at the Centre Hospitalier Universitaire de Sherbrooke, a nurse receives the video. There is a live exchange between both nurses regarding the progress of the wound healing and the treatment [67.29].

In Argentina, with the commercialized telepresence solutions from Cisco Systems, Dr. Juan P. Garrahan, in the Paediatric Hospital of Buenos Aires uses it for diagnostics, monitoring, and second opinion. Garrahan claims that 85% of consultations do not require a referral to the hospital [67.30] and in many of those cases the telepresence can be an ideal solution considering that Argentina is 3000 km long.

Fig. 67.11 TopCare kiosk (Fraunhofer Institute, St. Ingbert, Germany)

Telemend is a project funded by the EuropAid Cooperation Office. It has the objective of leveraging telemedicine tools to diagnose infectious diseases (malaria) in Colombia. It used TopCare Kiosk [67.31, 32] (Fig. 67.11) in remote areas of Colombia (Buenaventure and Guaviare). The kiosk is a PC equipped with a microscope, a blood analyzer, and an x-ray scan. The kiosk is manipulated by a nurse who will add the picture taken from a blood sample viewed from the microscope to the patient file. The information is then sent via a mobile network to a remote server, which allows any authenticated doctor to access the information in order to provide a diagnosis or monitor treatment.

Fall Detection

Description. Falls are an important problem in all modern societies. A report presented in 2007 in the WHO Global Report on Falls Prevention in Older Age states that 28–35% of people above 65 suffer a fall each year [67.33]; the number increases for seniors above 70 years old, since the percentage increased to 32-42% [67.34]. These falls are cause of hospital admission in 1.6-3.0 per 10 000 population [67.35] (data from Australia, Canada, and the United Kingdom).

Consequently, research and development has been trying to provide solutions to automatically detect falls in elderly people. The objective being to be able to identify premonitory symptoms of a fall before it occurs. Presently, fall detection causes numerous false-positives, and more reliable solutions are limited in their portability and/or cost.

Fall detection uses one or various portable and/or fixed sensor(s) that will identify the movement characteristics of a (several) body part(s), or the behavior pattern (e.g. electrical activity in the person's environment [67.36]). This information is then analyzed locally or remotely to determine the probability of a fall having occurred; if the outcome is a potential fall, then the notification system displays or sends an alarm, i. e. an SMS, email, or phone call.

The most common wearable sensor is a portable three-dimensional accelerometer. Possible environmental devices are video cameras, or presence sensors such as infrared or contact sensors (which will determine, for example, if a person is lying on the floor).

More accurate sensors include the monitoring of other parameters such as body temperature. Using accelerometers, it was also demonstrated that using two sensors positioned in different body areas is more reliable than using a single sensor [67.22], and it was proven that monitoring movements at the waist and head [67.37] provides more reliable information at other parts.

Examples. Vivago has chosen to identify a fall by looking into post-fall symptoms using a watch that monitors wrist movements. A reduction or absence of movement during a predefined time will launch an automatic alert. The EU funded project SIMBAD is an example of environmental solutions. In this project, fall detection is performed using wall-mounted pyroelectric infrared sensors. These sensors capture and analyze the movements without the need for invasive environmental elements such as the video [67.38].

Bioparameter Monitoring (Prevention – Diagnostics – Monitoring – Treatment)

Description. Telemonitoring consists in remotely surveying the health status of a patient who is home or institution-based. In order for the monitoring to be data-based, it requires a medical device to regularly or continuously measure the patient's physiological parameters; it is especially pertinent for people with chronic diseases.

The advantages of home vital parameter monitoring are faster data collection and analysis, avoidance of travel time and costs, integration of the monitoring in the patient's daily routine, and the possibility for the health professional to visualize data over long periods of time.

The vital parameters that can be measured remotely are numerous; the most common ones are weight, glucose levels, body temperature, hcg (human chorionic gonadotropic) for pregnancy tests, cholesterol and triglycerides levels, blood oxygen saturation, blood pressure, and heart rate (ECG). The measurements can be taken continuously, at regular periods, or at random periods depending on the pathology, the patient profile, the sensors, and the medical need.

As mentioned in previous sections, some parameters are already widely monitored in self-management tools; in this section, the interest is within a medical usage. There are parameters that can, in certain cases, be meaningful to the patient, but in most cases the interpretation belongs solely to the health professional.

A solution that monitors physiological parameters will be normally built using the following four components:

- The vital parameter measurement: the patient parameter will be measured using a medical device. The devices will follow one of the three types of procedures: noninvasive procedures (no skin breakage or penetration), minimally invasive procedures (when the device goes under the skin but without open surgical intervention such as subdermal implants), and invasive procedures devices (requiring heavy surgical intervention and from medium to long-term hospitalization).
- Local and remote data collection: the data is collected at the patient location and then transmitted to a distant server to be treated.
- Storage and presentation: while monitoring, it is essential that the data be presented in a meaningful manner to the health professional and that it is archived to obtain history and trends that are useful for the monitoring and treatment of a patient.

The vision of the European Union is a future where patients will have a combination of wearable or implantable multisensors combined with environmental sensors [67.12], but there are still some years of development necessary to achieve this.

Examples.

Glucose Monitoring. For diabetes patients, it is a requirement (it is vital for type 1 diabetes or juvenile diabetes) to measure the glucose concentration in their blood. Presently, meters can undertake a correct reading with only 0.3–1 μl of blood, and provide the reading within 3–5 s, archiving up to 2000 readings. Normally, these devices are sold with software that organizes, presents, and can perform some basic analysis. A key feature is the possibility to share the date with health professionals. An example is the Contour USB glucose meter (Fig. 67.12), which resembles a common USB key.

There is also room for niche adaptations for certain populations. An interesting variation of the product described above was FDA cleared in December 2009. It is a glucose meter for children and teenagers, called DID-

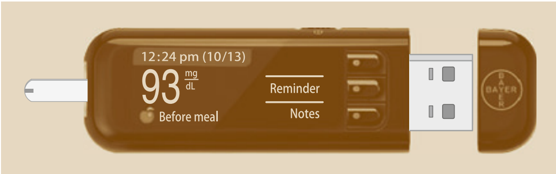

Fig. 67.12 Bayer's Contour USB glucose meter (Bayer Diabetes, Basel, Switzerland)

GET. It communicates with the Nintendo consoles DS and DS light, combining games to the readings. It includes web access to a community and the possibility to be rewarded for the results.

Many current commercial solutions have the advantages of ease-of-portability and ease-of-connection to any PC. However, they are limited to the time of reading, for example, no reading is performed during the night while the patient sleeps. Consequently, for certain patients, there is a need for continuous glucose monitoring systems (CGM). These systems continuously track the glucose level without patient intervention [67.39]. They use a sensor inserted under the skin (normally injected by the patient him or herself, refer to image below). The inserted sensor collects the measurement and communicates it to a local receiver/transmitter that then transfers the data directly or via a wireless terminal (mobile phone). The visible data can be sampled every 1–5 min.

Presently, when using a CGMs, the patient needs to replace the injected sensor every 5 to 7 days. Additionally, their accuracy has not yet reached that of traditional blood testing readers, needing calibration with a traditional blood strap reader. The CGM products are Abbott's FreeStyle Navigator, DexCom's Seven+Plus (Fig. 67.13), and Medtronic's Guardian.

Some examples of noninvasive CGM exist, e.g. a watch that uses low electric current to pull glucose through the skin (GlucoWatch G2 Biographer, by Cygnus). However, the FDA was not fully satisfied since it caused skin irritation in 50% of patients and the readings for low glucose levels were not precise. The product is no longer commercialized but developments around it continue [67.40].

Heart Rate Data Monitoring. Heart rate monitoring has been done for many years, i.e., measuring the heart rate or the more detailed ECG. Due to electrodes, microelectronics, and communications developments, the once cumbersome heavy devices that the patient carried for couple of hours while the device stored the data, are being replaced by real-time highly-portable solutions, some with basic automatic analysis. There are many advantages of monitoring real-time heart activity, such as the immediate detection of an issue, the monitoring of the outcome of treatment, and the efficient collection of information for research purposes.

Fig. 67.13 DexCom's Seven+Plus sensor insertion (source: DexCom, San Diego, http://www.dexcom.com)

The efficiency has also been clearly observed: a European trial concentrating in heart diseases was performed with patients leaving the hospital after a stay longer than 48 hours. Three groups were compared: a group receiving traditional care, a group receiving nurse phone support, and finally a group using a telemonitoring system. This system included a pressure, weight, and ECG home monitoring device. The data collected from these devices was sent via Bluetooth to a hub that used the fixed line to transmit the information to a server. The server presented the data to a nurse or technician (care manager) who escalated, if required, to a physician. This study lasted 2 years and accepted 426 patients. The study conclusion was that the nurse service group and the telemedicine group had a lower level of mortality (16–18%) among patients compared to the status-quo care [67.41].

A new stage on portability is the integration of electrodes into textiles (smart textiles) [67.42], e.g. the VitalJacket (for up to 5 d monitoring and 72 h battery autonomy) commercialized by Biodevices (a spin-off of Aveiro University) [67.43]. The Fraunhofer Institute has developed a smart textile ECG monitor using a proprietary mobile terminal and electrodes claimed to be flexible, biocompatible, and biostable [67.44].

Smart textiles facilitate the portability, however, implanted solutions are the next step. At the end of 2007 an implanted ECG monitoring system received FDA clear-

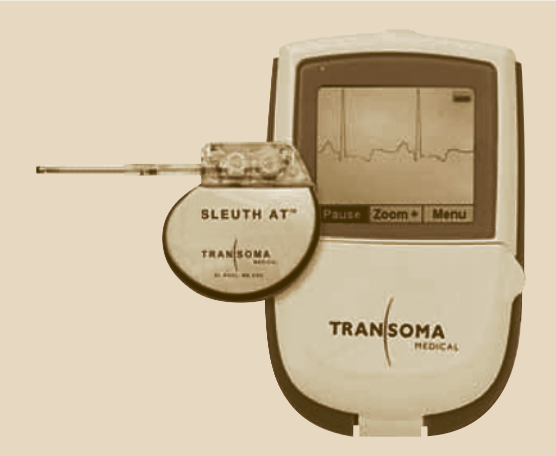

Fig. 67.14 The Sleuth implanted sensor and the handheld wireless receiver (after [67.45])

ance. The Sleuth ECG monitoring system manufactured by Transoma Medical (Fig. 67.14) was first implanted in 2008 with US patients for arrhythmia detection or monitoring; the implant done by Dr. Daoud and Dr. Hummel at The Ohio State University Medical Center in Columbus. The information was regularly collected and sent to a monitoring center where cardiac technicians filtered information before sending reports to the health professionals.

Dr. Daoud stated that [67.47]:

> *The Sleuth implantable recorder and the wireless communication system provide excellent recording fidelity and ease of transmission of ECG data that is continuously monitored and stored. Also, I can select the arrhythmia detection parameters, and the telemetry tracings are promptly sent in a user-friendly report, making it easy for me and my staff to care for our patients.*

Transoma Medical is, unfortunately, an example of the lack of synchronization between covering healthcare needs and finding a workable business model, despite the success and medical acceptance of their solution, in December 2009, Transoma ceased operations *due to the difficult market conditions* [67.45].

Despite the shown benefits, there are still a few large deployments, but some regions are more active. In Brussels, for example, 500 patients are participating in the *Belgium Heart Failure Project* [67.46] to reduce heart failure spleen mortality. Instead of using ECGs, the patients are provided with a tensiometer and their mobile phone for an SMS communication.

Sleep Apnoea Detection. HealthGear is a system tested to monitor sleep apnoea using a set of sensors communicating the data via Bluetooth to a smart mobile phone that archives, transmits, presents, and performs a basic analysis of the data received [67.48]. The sensor used for sleep apnoea detection is an oximeter for blood oxygen levels and pulse; however, the architecture could support multiple sensors. It was tested with 20 individuals, with very positive outcomes regarding usability; 100% participants declared themselves willing to use it and to recommend it, and the accuracy of the readings and analysis correctly identified cases of obstructive sleep apnoea (OSA).

Others. There are portable solutions that monitor different vital parameters; however their capabilities have not been used in full. A commercially available application is Equivital, with a two-lead ECG, temperature, and movement sensors. It monitors the heart rate, the ECG, the respiratory rate, body temperature, and movement/body orientation (Fig. 67.16). It uses a chest strap that collects information and uses bluetooth to send the data to a local PC or a gateway that then sends it to a remote server. This multisensor device is mainly used by military personnel and professional sportsmen, but its application in the medical area is still underdeveloped.

Auto Adaptive Treatment Systems (Diagnostics – Treatment)

Descriptions. Auto adaptive treatment occurs when a treatment is capable of changing itself based on real-

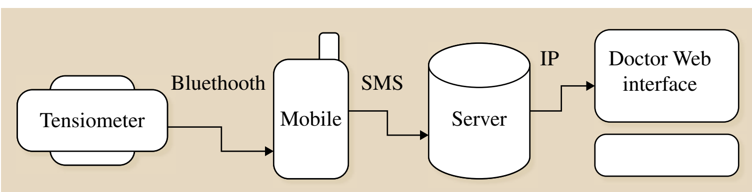

Fig. 67.15 The Belgium heart failure project (after [67.46])

Fig. 67.16 Multiparameter band strap (after [67.49])

time or delayed information. Note: teletherapy is used to define radiation that is performed at a distance from the body.

Once a patient has been diagnosed, the health professional will determine the most appropriate treatment. The determined treatment and/or therapy may be adjusted in light of the patient response, their efficacy, and secondary and adverse effects. Monitoring of ongoing treatments or therapies and patient response are valuable for adjusting treatments and may even be crucial in cases of extreme medical condition or disease. For example, after a quadruple by-pass surgery, round the clock monitoring of the patient may be essential to ensure that there are no complications, especially when the patient is discharged from hospital.

The ideal case is a continuous monitoring feeding and modifying the treatment as needed, and the whole real-time. Typically, for example, adaptive treatment would enable patients with Type 1 diabetes to have insulin injections based on real-time continuous measurement of their blood glucose levels. Another example is having pumps for patients following cancer therapy, adapting the dose and time of medication based on the real physiological patient needs.

Figure 67.17 illustrates the common elements of auto adaptive treatment systems. Namely, a sensor(s) that collects the vital parameter(s), the analysis algorithms that will define the preferred action (reduction/increase/pause of dose or example), and the delivery treatment device that will behave based on the analysis outcome. If the analysis is done at a distant site,

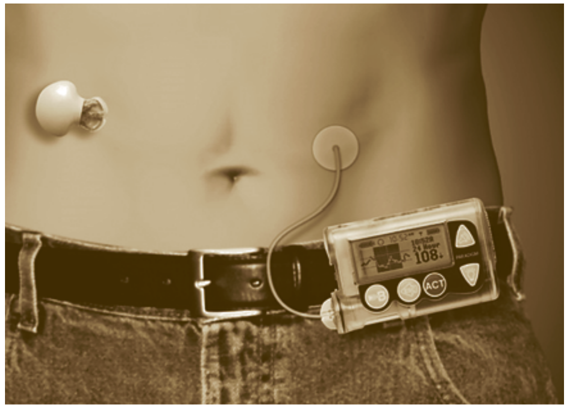

Fig. 67.18 The MiniMed Paradigm real-time system (after [67.50])

an additional component will be required: the communication channel with its transmitter/receiver both at the patient side and at the remote side.

Examples.

Diabetes. An automatic system for Type 1 diabetes patients is commercially available. This is the MiniMed Paradigm Real-Time system (Fig. 67.18), which consists of a continuous glucose meter (CGM) that monitors the glucose level. With this information the controlling device adjusts the delivery of insulin of the insulin pump [67.39].

Depression. A very different type of treatment relates to psychiatry with depressive patients. The adapted treatment was not the medication but the psychiatric sessions that were performed remotely. A comparative study was done for 6 months to evaluate the outcome of on-site treatment versus telepsychiatry (videoconference between the patient and the health professional). During 6 months, 119 depressed veterans followed either the traditional psychiatry follow-up or remote treatment. The treatment consisted of psychotropic medication, education, and short supportive counseling. The conclusion of this study was that remote treatment of depression using telepsychiatry compared with face-to-face treatment is equivalent from adherence, patient satisfaction, and costs perspectives [67.51].

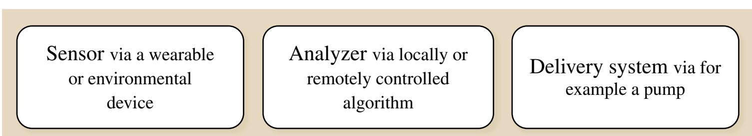

Fig. 67.17 Elements of an adaptive treatments system

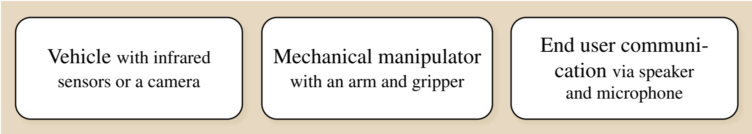

Fig. 67.19 Elements of a nurse robot

Wound Management. There are still but few examples of solutions; however different research groups are working around subjects that directly and indirectly will lead to solutions. The University of Rochester in the US is developing smart bandages with optical sensors that can monitor a change in color [67.53]. In the future, we expect to see the information collected, transmitted, and analyzed remotely, opening the possibility to automatically adapt treatments.

Robotics (Prevention – Monitoring)

Description. This approach consists of the use of robots to help perform certain basic caring actions at the patient's home, at institutions, and at hospitals. Robots are machines that operate autonomously, repetitive, programmable, or adapted tasks. Robots can do repetitive tasks (reminders, medication delivery, cleaning), specialized activities (move [67.54] or guide [67.55] a patient), interactive actions (keep a conversation), or be the communication gateway with health professionals. Most of the study outcomes show patient acceptance [67.55, 56]. In hospitals and institutions, robots help partially solve the issue of the lack of enough appropriate resources.

Nurse robots are normally mobile machines requiring a vehicle to move around the house or hospital without bumping into fixed or mobile objects (Fig. 67.19). Another key component is the mechanical manipulators, for example, an arm to deliver a drug. Finally, the end-user communication element permits us to configure or give orders to the robot, or simply, to enter information for an exchange with the robot (e.g. for a conversation).

The robot is preprogrammed with various levels of adaptation based on:

- External actions
- External inputs
- History.

The country most advanced in the area is Japan, with the technological background and one of the oldest populations.

Examples. A joint project between the University of Pittsburgh and Carnegie Mellon University has created a robot nurse for elderly people. The project's name is NurseBot, and the first robot is Florence [67.57] (in honor of Florence Nightingale). Its tasks are:

- Medication and regular life reminders (e.g. drink, go to the toilet)
- Keep company via conversation
- Provide a camera, speakers, and a microphone to allow remote health professionals to see and talk to the person
- Simple domestic appliance manipulations, such as open or close the fridge or the microwave.

Samsung has developed Romi [67.52] (Fig. 67.20), a nurse robot with the participation of the nursing school and the psychology departments of the University of Auckland (for the nurse knowledge base). Romi is polyglot (eight languages) and has a camera for face recognition, a microphone for voice recognition, arms and hands, as well as speakers.

The tasks are to:

- Deliver prescribed drugs
- Remind the patient of routines
- Motivate
- Keep a conversation.

Toyota has announced that their nurse robot will be commercialized in 2011, and Honda has spent hundreds of millions of dollars developing its human-like robot. Those are very promising news to see, in a near future, efficient and hopefully cost-efficient nurse robots in the market.

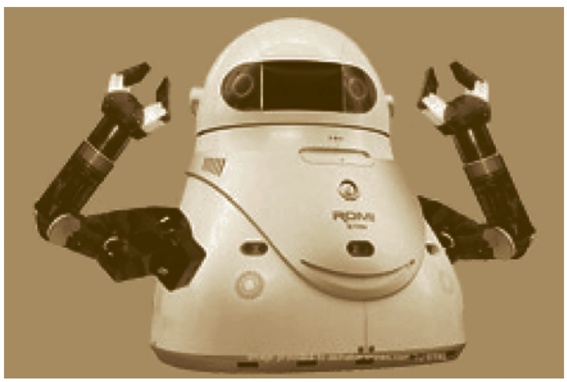

Fig. 67.20 Romi nurse robot (after [67.52])

Fig. 67.21 European project IWARD (intelligent robot swarm for attendance, recognition, cleaning, and delivery) (after [67.58])

The European project IWARD (intelligent robot swarm for attendance, recognition, cleaning, and delivery, Fig. 67.21) is targeted to providing help to institutions, clinics, and hospitals to overcome staff shortages [67.58]. The task is:

- Delivery of objects from point A to point B
- Cleaning
- Patient guidance within the establishment
- Detection of patients in unusual positions, e.g. patients sitting on the floor.

Teleconsultation (Prevention – Diagnostics –Treatment)

Description. For remote or rural areas where health professionals and specialists are not available, the possibility to perform a consultation with a remote expert is essential for the patient (he or she obtains a faster diagnosis and, if needed, treatment) and for society (to provide equal health access to all individuals while managing the health budget).

Another scenario where teleconsultation is important is during the second opinion procedure, since it normally involves two persons who are physically distant. The number of multipathologies patients is increasing with chronic diseases and ageing populations; consequently, different medical specialties require provision of an input to the diagnosis and treatment in order to treat the individual as a whole and not just an organ. The teleconsultation can consist of a phone call, an email exchange, or a chat. However, normally it involves some kind of image/video and/or sensor data exchange.

Examples. A teleconsultation project was carried out in Aarhus, Denmark (collaboration between the local hospital and university), for diabetic patients suffering from foot ulcers. The regular treatment was once a day or every other day. Moreover, twice a month the nurse organizes a remote consultation with the hospital doctor using a visio-phone. The experimentation was in 2005 and at the end of it the hospital decided to integrate the procedure to its regular operations [67.60].

A pan-European project was launched in 2005 with the name Medical Care Continuity project. The objective was to improve the follow-up of patients following the discharge from hospital. It uses a video camera that can be remotely directed by the health professional. Italy claims that these types of initiatives have reduced hospital stays by 22 days and cut hospitalization costs in half [67.61]. Maybe the Italians overestimate the benefits, but the gain for patients and hospitals is certain.

It has been seen that there are not many AAL and PHS commercial off-the-shelf products; this is changing. In 2008, Intel's Health Guide home terminal received FDA approval; it was designed for chronically ill patients to communicate with their health professional (Fig. 67.22). It has:

- Two-way video capabilities
- Interfaces with sensors (e.g. heart rate, glucose meter, oximeter) to capture the information and

Fig. 67.22 Intel's Health Guide terminal PHS6000 with tactile screen (after [67.59])

communicate to the health professional via a centralized server
- A calendar with potential reminders
- A collection of image, sound, or video education material
- A tactile screen.

It has a convenient size of 280 mm × 90 mm × 270 mm, however, it requires a broadband network connection such as ADSL, which limits the usage to home use. This terminal can be used for consultations and monitoring. A study with 200 patients above 60 started in 2010, in collaboration with General Electric and the Mayo Clinic to measure the reduction of hospitalization and emergency entries [67.59].

Telesurgical Assistance (Treatment)

Description. Telesurgical assistance is the action of performing a surgery locally with partial or total remote input. The remote involvement may consist only of a verbal opinion based on the images or sounds received, but it can go to fully controlling the surgery. Telesurgery is presently not used in AAL since it requires a setup and environment that for the moment is only possible at hospitals. However, as technology evolves, we believe that simple minimally-invasive interventions will be performed at home with the help of a trained nurse on site and experts at a remote site.

Components. An Austrian study demonstrated that remote-controlled navigation arthroscopies are reliable and accurate even for small joints (the temporomandibular joint, a facial joint) [67.62]. The same outcome was observed with a comparative local and remote intervention of 50 patients (Nissen fundoplication). The mortality was nil for both groups, and a 22 month follow-up showed comparable symptoms. However, the costs doubled for the remotely operated group with a longer time required (40 min) [67.63]. The costs and time would decrease as more remote interventions are done.

Smart Homes (Monitoring– Prevention – Diagnostics –Treatment)

The smart home relates to the home that is capable of quickly detecting a problem and even of foreseeing it; the home that will react in the most appropriate manner to the event raised; the home that palliates the physical and cognitive weakness of the elderly inhabitant using technological solutions.

The objective is an equipped home that will maintain or increase the physical and social autonomy of the individual living at home. There is no a one-size-fits-all smart home, since it needs to adapt to the specific weaknesses and environment of the person. The smart home would be equipped with a mix of the solutions presented in this chapter, plus the services and other technological solutions related to the nonhealthcare aspects such as entertainment (TV, Audio), education (TV, ...), security (closing and opening of doors/windows; intrusion detection and alert). The use of a single AAL service or tool adds a certain intelligence to the person's environment; the term smart home does not define a solution or approach but rather an attribute.

Despite the existence of standards, such as short-distance wireless communication protocols (such as zigbee, RF, or bluetooth), or standards for medical imaging (DICOM), the immediate and transparent interconnectivity of all needed components is not yet possible. There are associations such as Continua Alliance, IEEE, and mHealth Alliance working around this subject, and consequently, it can be envisaged that in the medium-term, the interconnectivity will be a pure plug-and-use.

Examples of smart-homes projects are Monami [67.64] and i2home [67.65]. The concept of the smart home was also used in a post-operative situation, where the physiotherapeutic exercises were automatically evaluated and the patient could receive feedback to ensure regularity and quality [67.66].

A subset of a smart home is the automatic adaptive environments. There are still very few environments that adapt themselves based on real-time healthcare personal parameters. There are some solutions that allow remote control of electrical or electro-mechanical devices; the control can be manually set or programmed based on the outcome of environmental sensors such as thermometers, light sensors, or fire detection (e.g. Biodom system).

The elements of an adaptive environment will be a sensor that captures health parameters, an analyzer that takes the information, determines the ideal configuration of the environmental device, and controls the device. It will, for example, adapt the heater to the body temperature of the person or the ventilation to the oximeter outcome.

67.3 Benefits and Challenges Ahead

Health and healthcare systems are complex interactions of biomedical, social, economic, ethical, and political factors. Significant advances in information communication technologies (ICTs) have made, and will continue to make, innovation in health technologies and equipment possible. ICTs have begun to positively impact the manner in which health systems provide products and services to patients, including through the development of the field of e-Health and through improved access and quality. More importantly, they hold greater promise for future improvements in health and healthcare systems. However, for e-Health approaches to provide viable and effective solutions to many of the current issues facing healthcare systems around the world, many conditions will need to fostered and brought together.

The future development and more pervasive adoption of e-Health approaches will depend on identifying where the benefits lie and the numerous challenges and issues that these technologies raise, as well as finding appropriate solutions. Some of the issues that are raised by e-Health technologies and equipment are common to other areas in the health field. For example, issues pertaining to the protection of patient privacy and confidentiality or informed consent are issues that arise within the provision of healthcare services generally. However, different facets of these issues may arise within the e-Health context. Other challenges are specific to the technologies used in and the services provided within the e-Health context and even more specific to AAL and PHS. For example, the reliability of the technologies and the consequences when they fail or the uncertainties pertaining to the legal framework are some of the issues more specific to this emerging field. Other challenges are themselves only beginning to emerge or will emerge in the future with the more widespread use of these technologies.

This section will draw attention to the numerous issues that legislators, political decision-makers, medical professionals, industry, engineering and systems design experts, patients, and civil society will need to consider and address to ensure the appropriate development, adoption, and usage of e-Health technologies and equipment.It will provide an overview of the different social, ethical, legal, societal, economic, and technological dimensions to the roll-out of e-Health solutions.

67.3.1 The Social Dimension

AAL and PHS, and e-Health more broadly, contribute to the achievement of many desired social objectives of improving healthcare services and products for patients and to improving the delivery of such healthcare [67.5]. From a patient perspective, such approaches may enable individuals to have better access to health information, to have better knowledge in regards to their health situation, to better manage their health, to have improved feedback on the impact of health services and interventions, and to make more informed choices about treatments and therapies.

From a health professional and healthcare system perspective, such approaches may enable health workers to make more effective decisions with respect to diagnosis, treatment, therapy, and monitoring. They may enable hospitals to provide higher quality and safer treatments and therapies. They may enable health professionals to contribute to addressing health problems of patients world-wide. They may improve the management of information and access to information for patient care and for administrative services. They may enable better and more timely mapping of public health threats, and they may enable improved training and sharing of knowledge along health professionals.

From a government and policymaker perspective, such approaches may enable governments to be more responsive to changing health needs. They may enable policymakers and public health authorities to be more aware of health risks, and they may foster the development of effective, safe, and efficient healthcare systems.

Stakeholders

The effective, safe, and efficient roll-out of e-Health solutions, such as those provided by AAL and PHS, will need to ensure that the appropriate people at the national, regional, and international levels are involved as early as possible. As such, it will be important for national and regional governments, all categories of health professionals, engineers, and technicians, patient and representative groups, industry, researchers and research organizations, international organizations, NGOs, and civil society to be implicated. Their diverse expertise, knowledge, technological know-how, partnerships, and investments will be essential for developing e-Health globally.

Developments and innovation within ICTs for e-Health and AAL will necessitate more effective involvement of SMEs. As agile entities they are able to make technical and business decisions more quickly and to execute them. Thus, they are better able to focus their research capacity. Well-financed SMEs are able to engage in high-risk, early-stage research and development, build strategic partnerships, and operate outside their local markets. As such, they have an important role in the development of future visions and in converting these into value propositions for patients and clients.

Participatory Involvement

Future innovation within e-Health will include engineering of context-aware and easy-to-use ICT systems that self-improve and self-adapt within their respective environments. Areas of research will include cognitive systems, interaction, robotics, and automation. For the innovations to be developed to be effective, efficient, and useful for the end-user, whether patient or caregiver, the participation of key stakeholders will be crucial. The development of technologies and the evolution of products and services will need to take into account user experience and future needs.

Carried out appropriately, stakeholder participation may be cost-effective, efficient, and eco-responsible in that the selection of technologies to be developed would reflect the needs of patients and their caregivers. Conversely, strategies that are not embedded in clear and realistic needs will be more vulnerable to failure due to lack of participation, acceptance, capacity, and other enabling factors.

There will be many challenges in carrying out stakeholder participation. Such testing will need to consider the breadth of possible users and that of possible uses. It will further need to consider the different conditions under which the technology should be used, the best manner in which to involve the testers and to simulate real world conditions and use, and the manner in which this testing respects legal and ethical frameworks. In testing AAL and PHS approaches, researchers will need to involve participants of the targeted patients. For example, elderly individuals, incapacitated individuals, or individuals with cognitive, motor, sensory, or neurological needs. As the testing will also need to assess usability, models developed involving healthy populations may not be reliable [67.67].

67.3.2 Legal and Ethical Dimensions

Existing medical and health sectors are amongst the most regulated and are covered by national, regional, and international legal instruments. Similarly, e-Health technologies are subject to the myriad of currently-existing national, regional, and international legal instruments. However, there is also a need for new policy, legislation, and regulation specific to address issues arising from e-Health technologies. Some areas where policy and legislation need to be considered include ethical considerations, privacy, confidentiality and security, and cross-border issues.

Research, testing, development, and distribution of products and services within the field of e-Health must abide by the ethical and legal frameworks generally applicable to human subjects, medical products, and technologies. While this section will review the legal and ethical issues, it is beyond the scope of this chapter to exhaustively examine such issues or to review all of the applicable legislation In addition, many of the technologies will be used for or by individuals who are in a vulnerable state. For example, the technologies may be used for elderly individuals, for individuals with a specific medical condition or disease, or for individuals with motor, cognitive, or neurological needs. These patients may be more vulnerable and thus extra care and attention is needed to ensure the protection of such patients.

Within the principles applicable to human subjects, there is the notion of minimal risk. Minimal risk has been defined to mean that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [67.68]. This principle entreats that patients should be exposed to minimal risk. Where it is not possible to abide by the principle of minimal risk, consideration must be given to ways in which risk can be reduced or eliminated or, alternatively, consideration must be given to employing alternative approaches.

Within the medical and health context, the cornerstone of patient protection is informed consent. This principle is recognized in international legal instruments such as the UNESCO *Universal Declaration on Bioethics and Human Rights* (2005) and the *Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects* of 1964 (last revised in 2008). Informed consent is a complex subject rooted in the principle that patients should be provided with pertinent information by health professionals, especially in regards to the significant risks of a given service, product or technology, as well as of the risks of particular importance to that patient. The objective is to provide useful information to enable patients to make the best decision in regards to their health and well-being. As e-Health systems become more widely implemented and are able to generate improved health and medical information specific to a patient, this will facilitate the informed consent process. Conversely, the potential use of personal health information for numerous and diverse research purposes may make the informed consent process more difficult. As personal health information may be used for broad and diverse research purposes, obtaining the type of specific consent used in most jurisdictions may not be sufficient. Moreover, the issue of secondary use of personal health information and records also challenges the current informed consent approach. Consideration has arisen of whether there may be the need to develop alternative models of consent for such broad and diverse research [67.69].

Policy decision makers and legislators should also address the issue of the possibility of discrimination and stigmatization of patients and patient populations based on medical findings and discoveries. As personal health information is increasingly centralized and completed by medical history and family medical history, a fuller picture of the current and possible future medical conditions of patients may emerge. With this fuller set of personal health information coupled with the constantly emerging medical and health findings, there may be increased risk that patients sharing disease characteristics may be the subject of discrimination or stigmatization, including from employers, insurance companies, and the general community [67.70]. In the development of e-Health strategies, addressing such issues will by key to maintaining public trust.

Privacy, Confidentiality, and Security

AAL and PHS, and e-Health, technologies will generate personal health information and data that will be stored within databases. The term database is used as a generic, catch-all term. Other terms that are used to designate such databases include *health information banks*. This collection and storage can cover quite a large definition of personal health information and data. It can include data and information generated directly by AAL and PHS technologies. It can also include information and data retrieved or derived from other health and personal records and linked or incorporated within the databases. The aggregation of significant personal health information into one or more databases increases the risks of violation of privacy, confidentiality, and raises issues of data protection and security.

This protection of privacy and confidentiality and ensuring the security of data and information will become more pressing when cross-border exchange of personal health information will be common place. Patients are increasingly seeking medical treatments and therapies outside of their country of residence. In order to provide the most appropriate treatment or therapy, health professionals will seek access to the patient's personal health information. In addition to the technological challenges, such as interoperability, numerous legal and ethical challenges will also arise. For example, when there is divergence between the laws of the different jurisdictions, issues of predominance of law and private international law/conflict of laws will arise.

In order to protect patients and maintain citizen's trust, policy-decision makers and legislators should develop the necessary legal and regulatory framework specific to the e-Health context. While some jurisdictions have already enacted legislation adapted to the specific e-Health context, thereby ensuring accrued protection of the privacy of its citizens, many others [67.5] lag behind and must rely on existing legal framework. Other European countries are in similar situations; many developing countries have yet to adopt legislation specific to e-Health. The province of British Columbia adopted the *Personal Health Information Access and Protection of Privacy* in April 2008. British Columbia is the first province in Canada to create a specific legislative framework governing access and privacy for electronic health information databases [67.71]. Some key aspects for such legislation to address include ensuring that data and information are accorded the highest level of protection, ensuring that measures are in place dealing with unforeseen and unauthorized disclosure or breach of security measures, and ensuring that unauthorized access or disclosure is significantly dissuaded and sanctioned.

Some elements for consideration in the development of principles applicable within the e-Health context include the following:

- Measures should be undertaken to ensure the respect of the individual's rights and freedom.
- Patients should be provided with detailed information of the nature of each e-Health solution/device/application prescribed for their treat-

ment and use, the inconveniences, the type of information and data that will be collected, and the diverse possible uses. The patient's consent should be obtained for the use of the solution/device/application, the collection of the data and information, and its possible uses.

- Patients should be informed and be provided with the opportunity to consent in regards to which information and data will be collected from them and which information and data will be retrieved and derived from their other health and personal records. This information should also specify the manner in which these information and data will be stored and accessed (i. e., text, audio, image, video). Patients should also be provided with the opportunity to specify which type of data and information they do not wish collected or stored.
- Patients should be informed about the uses for which their personal health information will be employed and by which entities. Patients should be provided with the opportunity to consent to the type of entities who should or should not have access to their personal health information.
- Patients should be informed about how they can access their personal health information.
- Personal health information should be available in the official languages.
- Security measures should be put in place to ensure that inappropriate and unauthorized access to patients' information and data are thwarted. Clear accountability for the storage, use, transmission, and maintenance of the information and data should be established.
- Mechanisms should be put in place for recording patients' consents and for enabling patients to subsequently modify or withdraw their previous consents.

67.3.3 Societal and Global Dimensions

The provision of effective, safe, and efficient healthcare services and products is a concern facing governments worldwide. While the specific types of concern may vary from jurisdiction to jurisdiction, many concerns cut across borders and continents. For instance, the issue of ensuring the financial sustainability of the healthcare system is a challenge that all governments face and in the coming years must address. Similarly, the promises of e-Health technologies can also benefit each jurisdiction whether developed or developing, albeit in different manners. For example, a doctor in a distant community may use teleconsultation and videoconferencing to confer with a colleague on another continent in regards to the health of a patient. The doctor and patient may be in a distant community within a developed country, such as Iqaluit in the far north of Canada, or within a developing country, such as a remote village in the Democratic Republic of Congo.

E-Health technologies and equipment can lead to a positive impact on healthcare. They can contribute to improved prevention, diagnosis, consultation, treatment, cure, and monitoring and surveillance of patients both locally, remotely, and in distant locations. Moreover, they can contribute to improving healthcare through broad and improved dissemination of public health information to citizens, facilitating the sharing of information and training among health workers. For example, the Algerian government established the *Health Algeria* network, a tool for data collection and exchange among the different actors in the health sector. It has been evaluated as one of the most effective actions for creating the environment and backbone necessary for implementing e-Health, as well as for the adoption of AAL and PHS approaches [67.72]. Improved monitoring of the incidence of public health threats and more rapid, targeted, effective, and timely responses can also be achieved through such technologies and equipment. E-Health technologies can facilitate self-study, eLearning and further professional development, as well as foster more effective and targeted research and the dissemination and access to research findings [67.73].

For e-Health to become a positive and effective force in ensuring access to healthcare around the globe, each jurisdiction must contribute to achieving common goals and shared values. Public policy must support effective, safe, efficient, and equitable e-Health systems. They should foster the use of collaborative approaches for the development of e-Health systems. They should foster the development of e-Health technologies and approaches that are supportive of local cultures and languages and that are inclusive of all communities and especially vulnerable groups.

The viability and utility of e-Health in developing countries or in least developed countries is dependent on the accessibility of ICT and health technologies and equipment. As Table 67.2 illustrates, access to needed ICT equipment and technologies is very low in developing and least developed economies. Thus, for developing and least developed economies to benefit more fully from e-Health, many more challenges will need to be addressed. Moreover, due to market distribution and market power, developing and least developed

Table 67.2 ICT infrastructure and access: core indicators, aggregate values (after [67.74])

Level of development	Number per 100 inhabitants A1. Fixed telephone lines	A2. Mobile cellular telephone subscribers	A3. Computers	A4. Internet subscribers	A5. Broadband Internet subscribers	A6. International Internet bandwidth per inhabitant (bits)	A7. Percentage of population covered by mobile cellular telephony
Developed economies	51	92	62	24	19	4755	99
Transition economies	23	77	10	3	2	223	88
Developing economies	15	33	5	4	2	177	74
Least developed economies	0.9	10	0.7	0.2	0.0	7	59

economies face constraints such as insufficient telecommunications infrastructure, high telecommunications tariffs, inappropriate or weak policies, organizational inefficiency, lack of locally created content, and uneven ability to derive economic and social benefits from information-intensive activities [67.74].

Addressing these challenges should be an objective for the global community. Approaches that are available to a doctor in the Canadian far north should also be available to a rural doctor in the DR Congo. AAL and PHS technologies can bring needed healthcare services to the poorest populations located in the most remote, rural, and difficult environments. Equally, these technologies can relay news of health developments from the most remote and difficult to reach places to the rest of the world. For example, through teleassistance, health workers in remote areas in Uganda are able to immediately report incidences of communicable diseases such as cholera [67.74].

67.3.4 Economic Dimensions

The aim of e-Health is to contribute to providing effective, safe, efficient, and equitable healthcare. Within this context, AAL and PHS aim to support the decentralization of the provision of healthcare from an institutional setting to a home environment. These approaches provide some solutions for the elderly, incapacitated individuals, individuals recovering from a condition, surgery or disease, or individuals with cognitive, motor or neurological needs. These different segments will represent an increasing percentage of the population over the coming years.

Numerous pressure points militate for the rapid development of AAL and PHS technologies. The ageing of the population, the increased burden of chronic diseases, increasing longevity coupled with rapidly increasing costs all necessitate the reconsideration of the approaches used within healthcare systems. In 2005, 133 million Americans – almost 1 out of every 2 adults – had at least one chronic illness [67.75]. Each year, 7 out of 10 deaths in the United States are from chronic diseases. Heart disease, cancer and stroke account for more than 50% of all deaths each year [67.76]. In Europe, chronic conditions account for up to 86% of all deaths [67.77]. This disease burden coupled with the factor that many patients live longer means that patients will require more diverse services and support from healthcare system.

Increasingly, with a cost-containment objective, patients are being discharged from a hospital context much earlier once their condition has stabilized. Thus, the patient recovery or convalescence is shifting increasingly to a home environment. In the United States, for example, the expenditures for home healthcare rose from 12.6 billion USD in 1990 to 59 billion USD in 2007 [67.78]. As the number of patients being cared for within a home environment grows, there is an increasing need for e-Health approaches to be developed and in place to ensure the delivery of effective, safe, efficient, and equitable healthcare.

In parallel, with a system that is not able to provide all of the required services coupled with the falling number of health professionals per patient, increasingly, we are witnessing the emergence of the phenomenon of family members and other persons becoming caregivers and providing the necessary services. Such situations have led to an increase in emotional, physical, and financial stress, which in turn has often resulted in health problems for the caregivers. For example, a US National study reported that 15% of caregivers came within this category [67.79].

Primordial for the successful adoption and use of AAL and PHS approaches, and e-Health more generally, is the consideration that the benefits to the participants in the system must be greater than the investments. Benefits may be considered on a short-term scale. For example, the implementation of only one PHS approach, such as videoconferencing, may be beneficial and even cost effective. However, benefits should also be considered from a long-term and holistic approach. The participants for whom such a system should be beneficial include the patients, health professionals, public health authorities and governments, researchers and research organizations, and industry. Investment may include not only monetary contributions but also contributions in terms of expertise, knowledge, know-how, professional resources, time, and materials. Similarly, in evaluating whether the investment of resources will be effective and efficient, a holistic and long-term perspective would be adopted.

Increasing evidence is emerging that the appropriate use of e-Health technologies can lead to improved delivery of healthcare while improving efficiency. In the United States, recent studies have determined that the national implementation of fully standardized interoperability between healthcare providers and key categories of entities (e.g., specialists, laboratories, and insurance funds) may yield savings of approximately $US 75 billion annually [67.80]. An evaluation of the e-Health approaches implemented within the province of Ontario, Canada, demonstrates the positive results in creating efficient structures while providing effective healthcare services [67.81]. They found improvements in safety and quality of services, such as 35–70% reduction in hospital admissions due to adverse drug reactions, 20–40% increase in immunization compliance, and reductions in avoidable hospital admissions and length of stay. In regards to chronic disease management, due to e-Health approaches, the province was able to increase annual eye exams for diabetics by 20–40% and decrease by 25–50% emergency room visits for asthma sufferers. The province was able to improve access to healthcare for patients in remote areas by increasing the teleconsultations by 10–20%. Through e-Health approaches, the province was able to improve efficiency, for example, by reducing by 5–15% lab tests through avoiding duplication and by increased efficiency of resource utilization (drugs and diagnostics). The e-Health system also enabled the province to improve accountability by facilitating the carrying out of evidence-based population health planning.

Patient and User Acceptance

AAL and PHS approaches, and e-Health generally, benefit patients by providing them with prompt access to their medical history, health-related and medication information, electronic communication, and decision support services at the point of care. These readily available resources help facilitate the health care delivery process, and have been found to have a positive impact on patients' health outcomes, well-being, quality of life, hospital readmission rates, and mortality rates [67.82–85].

While the potential for using such approaches to improve clinical care or patient self-management has been acknowledged by many professionals, patients may not accept these technologies for diverse reasons. The question of patient and user acceptance is a complex issue that involves human emotive and cognitive reactions. Moreover, a distinction exists between patient acceptance of a technology and patient use of the same technology. Studies have found that factors such as poor device usability, insufficient training, lack of skills, and low self-efficacy can dissuade patients from accepting and using such technologies [67.86, 87]. Motor, visual and auditory, cognitive, external, and health limitations must all be taken into account in the design of AAL and PHS approaches [67.88].

Patients' decisions to accept technology may also be related to their diseases and health conditions, attributes of the health technology itself, organizational factors such as support, the environment of use, the patients' personal characteristics, and social influences [67.67, 89–92]. Studies have shown that patients who consider themselves knowledgeable in regards to their disease and how to care for their condition tend to be more likely to accept e-Health technologies. There is a higher likelihood of acceptance of an e-Health technology by a patient if other persons they consider important thought they should use the technology [67.93]. Patients are more likely to accept and use the technology if they believe that it would be useful and that it would be easy to use. Patients are more likely to accept the technology if they believe that they are able to use the technology and that they have the resources to support its use [67.94–96].

While patient acceptance of the technology is crucial, acceptance and use of such technologies must also take into account the needs and considerations of health professionals, patients' caregiver, and public health authorities. For health professionals, reliability of the technology, utility of the measurements and data, and effectiveness of the technology are important considerations. Issues of ease of use, replacability/reparability, reliability, security, or costs are considerations for the caregiver. From the perspective of public health authorities, the elements of reliability and stability of the technology, its effectiveness and safety, the costs of the technology, training, replaceability, as well as the benefits of providing patients with more autonomy are of importance.

67.3.5 Technological Dimensions

The development of ICT technologies has made possible innovations in e-Health , such as AAL and PHS approaches. With these developments considerable benefits have emerged. However, as examined above, there remain many challenges to be addressed.

In order for such technologies to be widely accessible, challenges pertaining to connectivity remain. In order to enable connectivity, issues such as the lack of an enabling telecom policy and regulatory framework, lack of access to energy sources, such as electricity or alternative power sources, insufficient infrastructure and access, and high costs must be addressed for e-Health to be truly globally available. While these issues are more pressing for developing and least developed economies, they also need to be addressed by developed countries of considerable geographical size and with populations located in remote or distant regions.

The Issue of Scaling Up and Evidence Basis

Developing policy relies on the availability of strong, systematic, and objective evidence for and analysis of approaches that work and those that do not, and examination of the required conditions and frameworks. Within the context of ICTs and healthcare, there is currently a shortage of such systematic evidence and analysis, particularly for the application of such technologies at the population level. This is particularly apparent in regards to the scaling up of particular projects or pilot studies.

Many of the studies that have been or are being carried out are pilot studies or specific projects with a very limited scope. While such studies contribute to assessing and better evaluating the broader implementation of a specific technology, they may not be sufficient in providing a holistic view of implementing concurrently multiple approaches. While some approaches may themselves be effective and efficient, this should not lead to the conclusion that the implementation of other approaches would similarly be effective and efficient.

The large-scale roll-out of systems such as e-Health, involve significant investments and expenditures particularly of public funds. A key challenge facing governments and public health authorities is the development of a methodology that enables the systematic and holistic evaluation of how e-Health can be implemented to deliver the most effective, safe, and efficient healthcare services and products. Another key challenge is the consideration of which conditions and factors must be addressed in order for the scaling up of a particular approach within a holistic system to be effective and efficient.

Standardization, Interoperability, and Compatibility

As a fast-evolving field, many e-Health approaches and solutions face challenges in regards to standardization, interoperability, and compatibility. ICT standards are important in e-Health technologies as these approaches are heavily data and information driven and having seamless access to such information is foundational [67.97]. The lack of global standardization is a significant challenge for the effective use of e-Health technologies and approaches. For example, within Europe, it was found that there is a lack of widely used e-health standards, leading to problems with interoperability. Of the standards that do exist, the study finds that some are conflicting and many are proprietary [67.98]. The study also concluded that within a single health service provider, the standards currently used were supportive. However, the situation was unsupportive for cross-border care provision. One of the barriers identified to the adoption of international e-health standards in hospitals is hospital IT managers, who prioritize internal process functionality above commonly used standards. The respondents also agreed that managers lacked financial incentives to exchange information electronically.

Standardization/harmonization also applies to the data and information to be collected and entered into databases. For example, the lack of standards is a significant challenge in regards to ensuring the most effective and efficient use of data and information that is generated through e-Health approaches. If the identification,

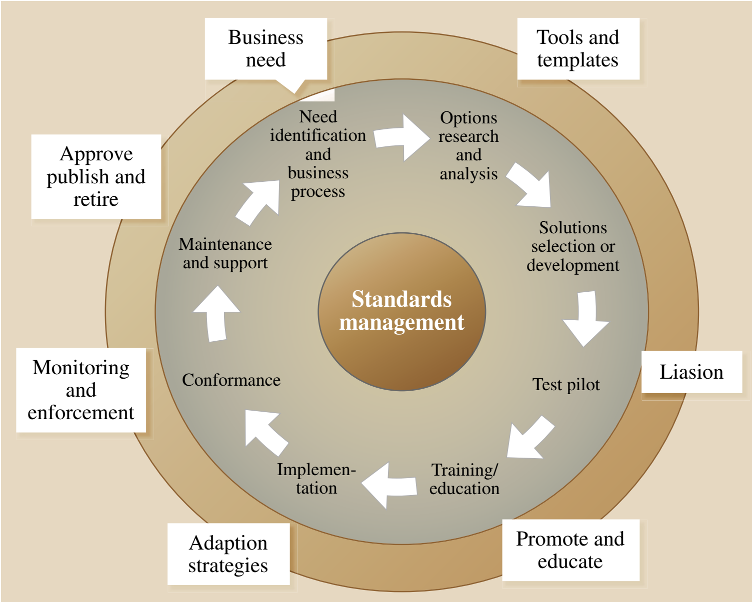

Fig. 67.23 Example of e-Health standards strategy (after [67.84])

Part F | 67.4

data entry, and classification of the data and information are not standardized, the potential for secondary use of such data and information may be limited. The issue of interoperability will also be key in ensuring that resources are used efficiently. Furthermore, as more and more patients choose to undergo medical procedures outside of their country of residence, international compatibility of information and data will be another significant challenge. As Fig. 67.23 illustrates, a viable approach to developing standards and to addressing issues of interoperability and compatibility necessitates a holistic perspective that takes into account the objectives and needs all of the actors and at the different stages of use.

67.4 Conclusion

67.4.1 Observations

As governments and public health authorities search for alternative means to deliver effective, safe, efficient, and equitable healthcare services and products, the use of information and communication technologies embodied in e-Health is a promising key area. While many aspects of functioning of healthcare systems will continue to need re-vamping, e-Health will enable a patient-centric approach wherein the patient is active in the management of his or her health, while improving efficiency and effectiveness.

The increase in computer and technology literacy offers the opportunity for better integration of healthcare delivery into daily activities. Future generation of patients will be more demanding in regards to information and options for treatments. AAL and PHS approaches will provide tools for patients and their caregivers to actively monitor their health status, to learn more about their condition or disease, and to understand how to better manage it. e-Health technologies can provide important support for the prevention, detection, diagnosis, treatment, monitoring, and surveillance of a patient's condition or disease. It will permit reaction and adaptation to the changing needs and situation of the patient. Moreover, it will enable adaption within a home environment.

The full implementation of e-Health will need the involvement of all actors within the health sector, whether private or public sector, at national, regional, and international levels. As e-Health holds promise for all populations, rural or urban, remote, or central, and within developing or developed economies, the efforts of implementing this set of technologies, applications, solutions, and devices need to involve the global community. e-Health may bring many benefits; however, its full implementation will need to address and find solutions for the numerous challenges. New approaches to developing technologies, policies, and legislation will need to be considered.

67.4.2 Areas for Further Work

For legislators, policy decision-makers, medical professionals, industry, engineering, systems and design experts, patients, international organizations, and civil society to be able to ensure the appropriate development, adoption and usage of e-Health technologies and equipment, many more areas of research will need to be addressed. Some of the gaps are listed here.

1. *Internationalization*: some of the most complex issues may need to be considered and addressed at the international level. For example, standardization, interoperability, and compatibility may be issues that are best addressed at the international level in order to ensure that information, data, and technologies can be used and exchanged globally. Another area where intervention at the global level may be beneficial is the development of international instrument(s) (i. e., convention, treaty, etc.) in regards to the issues such as privacy and confidentiality, data protection, discrimination, and ethical standards.
2. *Cost – benefit analysis and evidence*: the issue of cost and expenditures in regards to healthcare systems is a significant challenge facing every government as well as the global community. While many advocates of e-Health highlight the cost containment possibility of such technologies, it is an area that requires further and more in-depth study. Complex issues of measuring impact and savings will need to be addressed; frameworks and statistical methodologies will need to be developed.
   Simplistic approaches should be avoided as they will lead to inaccurate or incomplete evaluations. For example, some robotic surgery systems cost more than $US 1 million to purchase and more than $US 100 000 a year to maintain. Hospitals can save on costs by using such robotic surgery that is less invasive and thus, decrease the length of a patient's stay due to a shorter recovery period. However, calculations taking only this aspect into account may provide an inaccurate picture. Other considerations that could be taken into account include shortened surgery times, reduced fatigue of surgical professionals, reduced risk of surgical errors, etc. With other factors taken into account, the cost–benefit evaluation may be quite different.
3. *Privacy and confidentiality*: government decision-makers will need to develop policy for ensuring the protection of privacy and confidentiality of patients and the security of their personal health information and data in support of e-Health. In addressing these issues, they will need to take into account that patients are increasingly traveling outside their country of residence to obtain medical treatments and therapies.
4. *Standards, interoperability, and compatibility*: the development of internationally-agreed standards will be a key challenge whose resolution will need to be addressed in the near future. Consideration should be given to the manner in which international standard setting organizations can play a more active role in the development of global standards necessary for the effective and efficient development of standards, interoperability, and compatibility in e-Health approaches. Consideration should also be given to the use of open sources.
5. *Technological developments*: the evolution of information and communication technologies will contribute to improving the delivery of healthcare. While it is difficult to predict the evolution of technology, the development of some key areas should be considered [67.99–102]:
   - New, pervasive, and trustworthy network and service infrastructures to replace current Internet, mobile, fixed, and audiovisual networks, including research in regards to architecture
   - ICT based on nano-scale integration, new materials, photonics, and organic electronics, which will provide new types of devices and intelligent systems
   - Context-aware ICT systems that self-improve and self-adapt within their environments, including the fields of cognitive systems, robotics, and interaction
   - New technologies and devices that respect societal goals of sustainable development. Increasingly, electronic components, devices and systems will need to focus on being smaller, more accessible, more reliable, and greener.

67.4.3 Future Technologies

Wearable and environmental sensors. Smaller, lighter, more powerful sensors equipped with wireless connectivity, permitting the measurement of single or multiparameters, including parameters that can only currently be measured with large and complex equipment.

Human–machine interaction. Devices that facilitate human–machine interaction:

- *Displays.* New lighter, thinner, faster displays. Nanoemissive display and the surface-conduction electron-emitter display, both with higher contrast levels and faster response times than LCDs.
- *Very smart textiles*. Currently smart textiles used in healthcare are mainly passive smart (sense). In the future, they will be active smart textiles (sense and react) and very smart textiles (sense, react and auto-adapt).

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