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ALLADIN
Natural Language Based Decision Support in Neuro-rehabilitation

SPECIFIC TARGETED RESEARCH PROJECT
PRIORITY 2.3.1.11

DELIVERABLE 6.2:
CARE DELIVERY ASSESSMENT REPORT

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Scuola Superiore Sant'Anna

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List of Partners:	Arteveldehogeschool (B) Language and Computing NV (B) Budapest University of Technology and Economics (HU) Univerza v Ljubljani, Fakulteta za Elektrotehniko (SI) Zenon SA, Robotics and Informatics (EL) (University of Wales Cardiff (UK)) Multitel ASBL (B) The Provost Fellows and Scholars of the College of the Holy and Undivided Trinity of Queen Elizabeth near Dublin (IRL) Országos Orvosi Rehabilitációs Intézet (HU) Scuola Superiore di studi universitari e di perfezionamento Sant'Anna Universita' Campus Bio-Medico

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Authors:	Giuseppe Turchetti (SSSA), Eugenio Guglielmelli (UCBM), Silvia Petroni (UCBM), Ilaria Palla (SSSA), Stefano Mazzoleni (SSSA), Barbara Labella (SSSA), Sara Cannizzo (SSSA), Stefania Bellelli (SSSA)
Approved by:	
Distribution List:	WP6 partners, Project Coordinator, Project manager

Executive Summary

The goal of this document is to describe the activities performed in Task 6.2 by SSSA and UCBM teams from October 2006 to March 2007.
The main aim of the D6.2 is to outline the epidemiological and cost-related scenario in which the Alladin ADD has been developed; to identify the main factors of strengths and the elements to readjust in order to successfully manage the future commercialization of the ADD; to provide an operative tool and a theoretical model for the evaluation of the Alladin ADD costs and costs savings, once at its best running.
In details:

- *In the first section a review of the epidemiological and economic data about stroke is presented; the main published epidemiological studies have been analysed in order to estimate, basing on data about stroke incidence, prevalence, mortality and disability, the full market potential of the Alladin ADD. The cost categories of stroke have been defined according to the Cost-of Illness approach and a critical analysis of the most relevant published data about the total – and the social – cost of stroke is proposed in order to provide a general frame of costs – and potential cost-savings- related to the use of the Alladin ADD;*
- *In the second part of the work the results of a SWOT survey carried out within the Alladin Consortium are presented; a SWOT questionnaire has been defined and distributed to each Partner in order to investigate, from a multidisciplinary perspective, strength, weaknesses, opportunities and threats of the Alladin ADD.*
  Partners were asked to list, according to their experience, the main Strengths, Weaknesses, Opportunities and Threats of the ALLADIN system. The 90% of the total number of questionnaires submitted was received by SSSA/UCBM team for the analysis of the results. The results showed a prevalence in the number of strengths identified, with respect to the weaknesses, opportunities and threats. All Partners agree with the idea that is worth going on with the validation of the ALLADIN approach through further clinical trials. They also agree in the conviction that further technical improvements are needed in order to propose the system for certification and introduction on the market. On the whole, a general agreement on the advantages brought by the easiness of use and robustness of the system and by the use of natural language for describing patient's conditions has been expressed. The opportunity of using many data coming from different body districts has been highlighted. Each Partner is aware of the possible objections that the medical community may raise, towards the acceptance of this innovative approach in functional assessment. For this reason, they suggest dissemination and sharing of results, and training sessions among hospitals and rehabilitation institutes.
- *In the third section is presented an operative tool for the assessment of costs and cost-savings related to the use of Alladin in clinical practice and in comparison with the standard approach; the instrument, in the shape of a questionnaire, considers both the diagnostic and the rehabilitative stages of the assistive route for a stroke patient. Its main aim is to examine all the services provided and the human resources involved in the whole diagnostic and rehabilitative process, comparing the traditional techniques with the ALLADIN device. Particular attention is given to the analysis of the time spent for providing such services with the two methods. The questionnaire has been distributed to the clinical partners of the Alladin project and, basing on the obtained feedback, has been readjusted until to get the*

final version. The proposed instrument could provide useful information once applied to Alladin ADD at its full running.

- *In the last section a theoretical model is proposed for the assessment of the social and economic benefits of the Alladin approach if compared with the standard one. A traditional approach – "trial and error strategy" is compared to the Alladin one – "in progress evaluation", considering the diagnostic and the rehabilitative steps of the assistive route for a stroke patient. The model points out the potential social costs-saving related to the application of the Alladin approach. Moreover, under the consideration that higher severity of stroke implies higher level of disabilities and consequently higher levels of social costs, the model shows that the use of the Alladin ADD would be more "effective", from a social and economic point of view, in the case of patients with severe and very severe stroke.*

Deliverable D6.2 is the main outcome of Task T6.2 'Assessment of impact on care delivery', *led by Scuola Superiore Sant'Anna (SSSA), in close collaboration with University Campus Bio-Medico (UCBM).*

Scuola Superiore Sant'Anna (SSSA) team thanks to its academic expertise on economic studies on health care assessment mainly focused its effort on the review of the principal literature on epidemiologic data on stroke and on the cost of stroke (assessment and treatment). Relevant efforts have been devoted by the SSSA economic team for setting and developing the operative and theoretical models.

The questionnaire on the SWOT analysis of the ALLADIN ADD and end-products and the questionnaire on the estimation of potential cost savings of the ALLADIN ADD and end-products was leaded by SSSA team, in collaboration with UCBM team.

University Campus Bio-Medico (UCBM) mainly focused to the analysis of the results from the two questionnaires .

This deliverable has been developed during the third year of the ALLADIN project (Months 33 to 38) by the WP6/T6.2 Team directly joined by two Alladin partners (SSSA, UCBM). According to the ALLADIN multidisciplinary approach, T6.2 has been carried out in tight co-operation with the project co-ordinator, also asking feedback for the validation of the proposed approach by the other ALLADIN partners for the SWOT analysis and the clinical partners (AHS, NIMR,TCD) for the analysis of potential cost savings. The final approach selected for the assessment of care delivery is mainly based on the specific agreements which were achieved during the OCB meeting held in Athens, November 30-December 1, 2006 .

D6.2 - Table of Contents

1 The complexity of the innovation process in healthcare: an introduction to the Deliverable 6.2

Starting from the assumption that the introduction of new and advanced solutions in every industrial sector is a complex process, advances in biomedical technology are usually more difficult to achieve than in other fields. Several elements, in fact, may be identified as factors contributing to the complexity of the innovation process in the biomedical sector:

1. *Multidimensionality of the problems*
2. *Multidisciplinary approach*
3. *Conflict of interests and resistance (inertia, path dependency, position rents, etc.)*
4. *Differences in the incentives and time horizon of various players and stakeholders (researchers, companies, payers, consumers, society, etc.)*

And several questions may be considered still opened:

How research/innovation strategies/trajectories are defined?

How to transfer innovation from research to industry (how to "industrialise" the research results)?

How to do it in a successful way?

The innovation process for the development and production of biomedical technologies, as for most other new products, is made up of numerous steps (Figure 1).

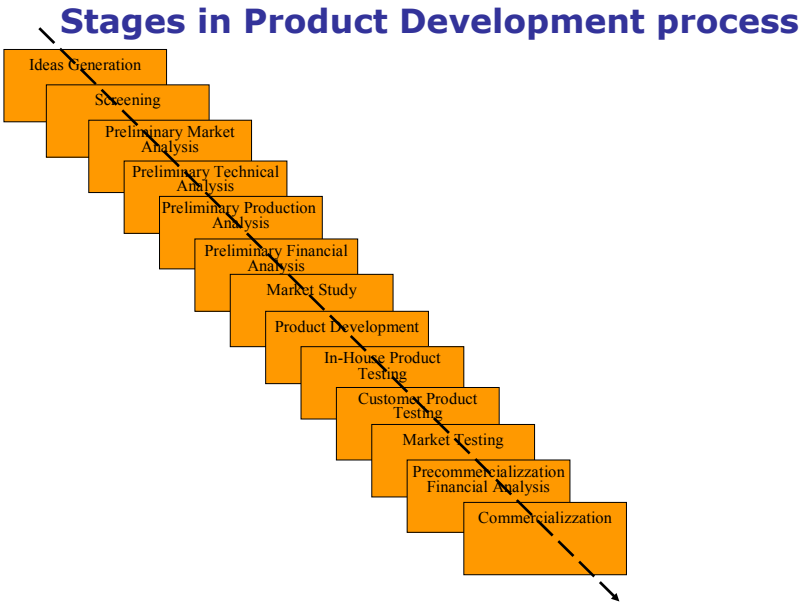

Figure 1. Stages in the product development process
(Source: L. Rochford, W.Rudelius, New Product Development Process, 1997)

And many stakeholders are involved in each of the above steps for new biomedical technologies production:

- *health product makers,*
- *regulators,*
- *clinicians,*
- *patients,*
- *hospital managers,*
- *payers,*
- *governments,*
- insurers.

The presence of different interests, the need for a coexistence of several scientific backgrounds to be effectively melted and the need for a strong coordination between the technological dimension and the clinical dimension, make the management of the technological innovation process in the healthcare field particularly complex.

Furthermore, we can not forget the social and ethical implications of health related activities in our contemporary world following the evolution of social concept of health. Health, in fact, is intended as more than a battle against both physical and psychological illness. In many Countries (especially where the welfare state plays a relevant role) it represents a person's right and a social interest.

Consequently, managing biomedical product development process requires to take into account all the following perspectives:

- Technological
- Clinical
- Economic
- Social
- Ethical
- Legal

Furthermore, these perspectives introduce new constraints/objectives of the innovation process that have to be considered:

- Efficacy
- Effectiveness
- Affordability
- Sustainability
- Equity
- Usability
- Market potential
- Accessibility

A multidisciplinary approach is requested from the very beginning of the innovation process and for each phase of the biomedical product development process.

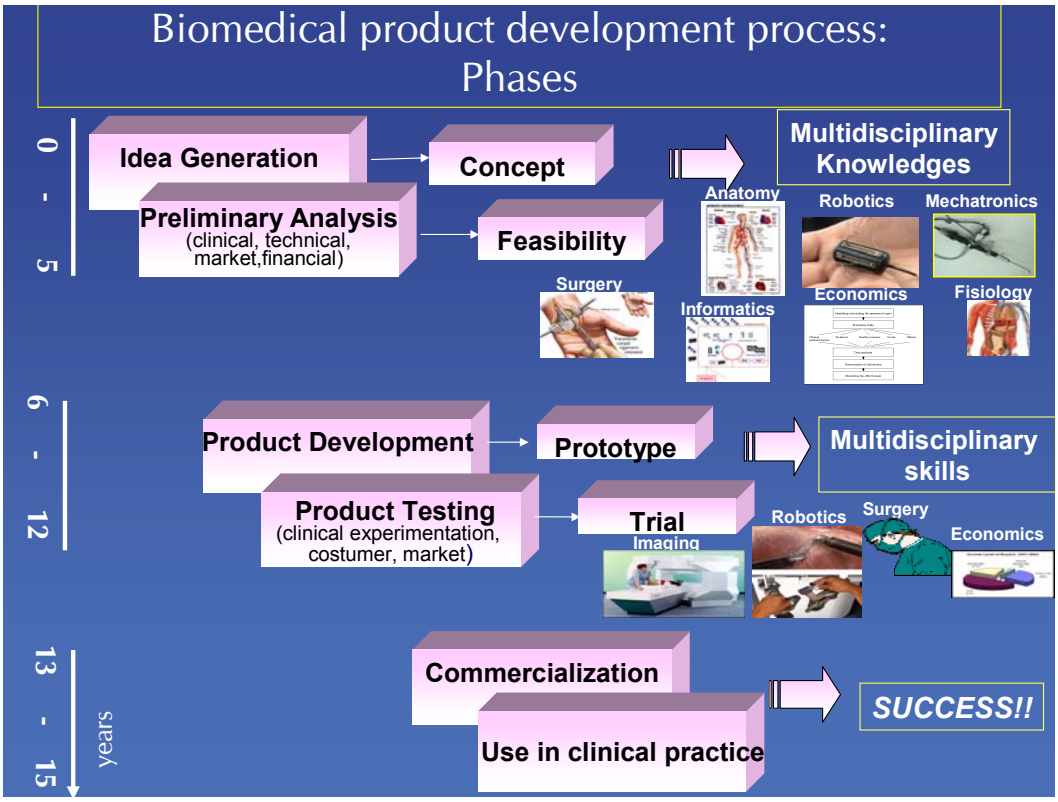

Figure 2. Stages in the development process of biomedical products *(Source: SSSA WP6 team)*

The D6.2 aims to approach stroke and the potential benefits of the Alladin ADD from an integrated and multidisciplinary perspective so to contribute to well framing the clinical, technological and economic scenario in which to move forwards the future/possible commercialization of the device developed and tested in the Alladin Project.

2 The problem of stroke recovery: an epidemiological and an economic review

2.1 Epidemiological context of stroke

2.1.1 Definition and subtypes of stroke

The World Health Organization (WHO) estimates that, every year, 15 million people worldwide suffer a stroke. Of these, 5 million are left permanently disabled and 5,5 million (3 million woman and 2,5 million men) die [1].
According to the WHO definition, a stroke is a clinical syndrome with "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin"[2].
The main subtypes of stroke are identified as ischemic stroke (infarction), hemorrhagic stroke (ICH) and subarachnoid haemorrhage (SAH). Baseline stroke severity is assessed using the National Institute of Health Stroke Scale (NIHSS) and, in agreement with the classification proposed by HS Jorgensen, it could be distinguished in four levels: mild, moderate, severe and very severe [3].
Among the total population of stroke patients, approximately 80% have ischemic stroke, involving the largest proportion of direct expenditure on stroke care, and 20% of all strokes are hemorrhagic. Of these three out of four are intracerebral hemorrhages, while the rest are subarachnoid hemorrhages, representing 5% of all strokes, as shown in Figure 3.

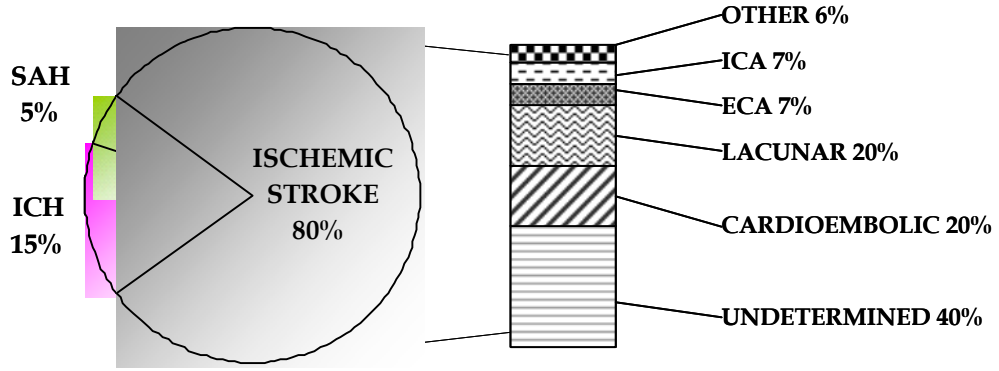

Figure 3. Causes of stroke: underlying types of ischemic stroke are shown in the bar graph at the right. ECA=Extracranical Carotid Artery Disease; ICA= Intracranical Carotid Artery Disease
(Source: American Heart Association, 2003)

An high percentage (40%) of ischemic stroke have unidentified cause, but these proportion could change as the ability to investigate the underlying causes of stroke improves [4].

In demographically developed countries, characterized by an older age structure, the mean age at which stroke occurs is around 70 years. In less developed regions, the average age of stroke will be younger due to the different population age structure resulting from higher mortality rates and competing causes of death.

2.1.2 Incidence of stroke

Incidence, prevalence and mortality estimates are quite different in the published international and national studies as they strongly depend on the composition of the reference population, in relation to age and sex, on type of stroke and the study design.
Recently, the American Heart Association estimates that each year about 700,000 people experience a new or recurrent stroke in the United States. About 500,000 of these are first attacks. Approximately 200,000 occur in people who have already had a stroke before. Men's stroke incidence rates are greater than women's at younger ages but not at older ages. [5]
Incidence data from countries with population-based epidemiologic surveillance systems such as Rochester, Minnesota (USA), indicate a decrease in rates in the late 1970s and early 1980s, followed by an increase in the late 1980s. This could be partly explained by the longer survival of patients with ischemic heart disease at risk of stroke [6] (Figure 4). The reclassification of stroke cause with the routine use of computerized tomography (CT) scan could explain in part the slight increase in the incidence of intracerebral hemorrhages.

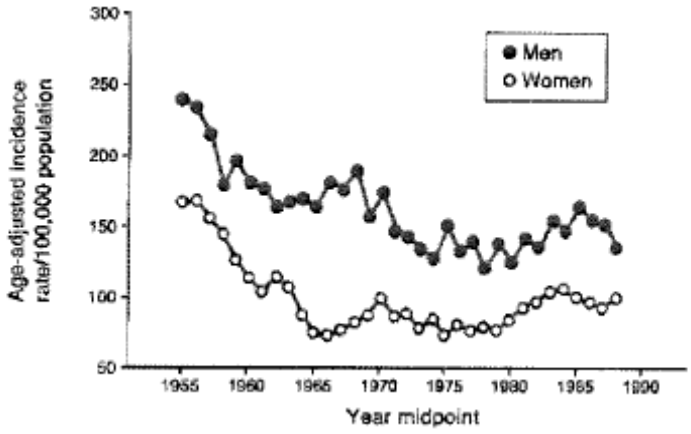

Figure 4. Age-adjusted incidence of stroke by sex, Rochester, USA, 1955-1989
(Source: Ingall T, J Insur Med 2004, 36)

Epidemiological studies have shown that incidence differ widely throughout Europe with marked differences between eastern (EE) and western European (WE) countries.
An east-west gap was confirmed by the EFNS Stroke Scientist Panel [7]. In 1997 crude incidence rates of acute stroke were higher for most eastern (range between 3.0/1,000 and 5.0/1,000) than western countries (range between 2.0/1,000 and 2.5/1,000), as showed in Table 1.

	Population in millions	Incidence	Prevalence	Rank as cause of death	Stroke patients treated in hospital per annum	30-day mortality (%)	Stroke patients not hospitalized (%)	Recurrent strokes (% of all hospitalized stroke patients)	Mean age (all stroke patients)	Hemorrhagic strokes (% of all stroke patients)
Austria	8.0	2.0–2.5	7.0	3	36.596	20	20–30	20	70	9
Belgium	10.1	2.0	2.0	3	20.000	21	–	30	68	10
Bulgaria	8.4	4.0	8.5	1	29.327	19.3	26.3	–	–	19
Croatia	4.7	3.0	8.0	1e	16.259	25	35	25–35	67.7	15.8
Czech Republic	10.3	4.5	5.75	3	58.000	25	2	20	–	30–35
Denmark	5.2	2.0	5.0–8.0	3	12.500	20–25	12	20–25	71–74	15
Estonia	1.5	2.5	–	2	3.037f	30.2	23f	–	64	–
Germany	81.6	1.7–2.5	4.2–7.5	3	150.000	20	25	3–15	71.7	14
Greece	10.4	2.1	7.9	–	–	–	–	–	70	15
Hungary	10.2	5.0	–	3	50.722	10–25	–	–	66.7	15
Israel	5.4	2.0–8.0	–	3	13.000	13–14	10	–	72	10
Latvia	2.5	–	–	2	5.071	33	–	18.8	–	21.4
Poland	38.5	1.5	–	4	50.000	21	15–20	10	71	10
Portugal	9.9	2.0	8.0b	1	29.054	17.7	20	–	–	18.3
Russia	147.0	1.9–2.5	5.0–6.0	2	160.000	35	60	–	–	–
Slovakia	5.3	3.0–5.0	5.0–7.0	3	15–20.000	15–20	10–15	10–20	60–65	15
Slovenia	1.9	1.9	–	3	3.202	21	20	20	63.2	16
Spain	39.1	2.27	40.1c	1d	–	12.1	–	25	65.6	16.8
Sweden	8.7	3.0	4.4	3	25.000	12	–	50	75.3	10
Switzerland	6.9	1.0–1.5	3.3	3	12.000	6	5–10	25	63	11
Turkey	60.5	0.8–1.7	7.7–15.6	4	93–124.000	15.1–19.7	–	16.2	65.5	19–27
UK	58.3	3.75a	15	–	130.000	20	20	20	72	10

[a]45–84 years. [b]>50 years of age. [c]45–84 years. [d]45–84 years. [e]Only females, in males stroke ranks third. [f]First-ever strokes only.

Table 1. Clinical Epidemiology of stroke in Europe, 1997
(Source: Brainin M et al, European Journal of Neurology, 2000, 7)

Most countries with an high case fatality had an higher proportion of hemorrhagic strokes, a lower hospitalization rate for all strokes and an higher prevalence of known risk factors.
The most recent Italian Guide Line for stroke "Stroke Prevention and Educational Awareness Diffusion" (SPREAD), indicates that 196,000 cases of stroke occur in Italy every year, 80% of those are first occurrence of stroke and 20% are relapses. 39,000 persons with stroke die in the first month after the event and other 58,800 survive with disability [8].
Italian population-based crude incidence rates are available for six stroke registries and range from 1.79/1,000 in Vibo Valentia to 2.92/1,000 in L'Aquila.
Incidence rates increase with age; in regard to persons aged from 65 to 84 years, an European population-based study indicates that the incidence rate is 8.72/1,000 with a corresponding 95% confidence interval (95% CI) between 7.47 and 10.06 [9].
In the same age class, data from the Italian Longitudinal Study on Aging (ILSA), suggests that sex- and age-standardized incidence rate of stroke is 10.47/1,000 (95% CI 8.63-12.32) as showed in Table 2.

Age class (years)	Sex		
	Men	Women	Total
	IR (95% CI)	IR (95% CI)	IR (95% CI)
65-69	4.54 (1.39-7.68)	4.58 (1.41-7.75)	4.56 (2.32-6.79)
70-74	9.53 (4.86-14.20)	8.10 (3.52-12.69)	8.86 (5.58-12.14)
75-79	20.0 (12.59-27.41)	12.72 (6.67-18.76)	16.44 (11.64-21.25)
80-84	15.27 (8.41-22.14)	13.46 (6.87-20.06)	14.39 (9.62-19.16)
Total	11.67 (8.95-14.38)	9.21 (6.73-11.69)	10.47 (8.63-12.32)

Table 2. Standardized incidence rates (IR) for stroke and 95% confidence intervals (95% CI) for the age class 65-84 years, by sex. Italy, 2001*(Source: Spread, 2005)*

2.1.3 Prevalence of stroke

The American Heart Association reports that among adults age 20 and older, the prevalence of stroke in 2004 was an estimated 5,700,000 (2,400,000 males, 3,300,000 females) [5]. Prevalence rates increase with age and consistently across age classes men have higher rates than women, as showed in Figure 5.

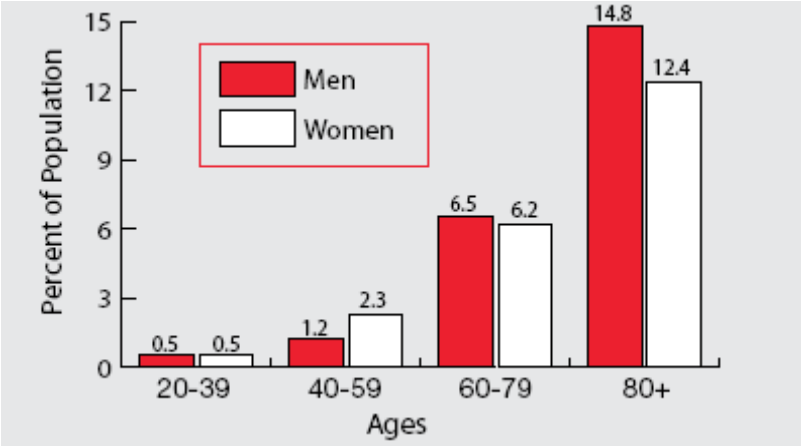

Figure 5. Prevalence of stroke by age and sex, USA, 1999-2004
(Source: American Heart Association, 2006)

Approximately 15 percent of all strokes are preceded by Transient Ischemic Attack (TIA). A TIA is a mini-stroke that lasts less than 24 hours. At 5 years, the risk of stroke occurrence is about 30% following either transient ischemic attack or stroke. In USA, prevalence of TIA in men is estimated to be 2.7 % for ages 65–69 and 3.6 % for ages 75–79. For women, the prevalence is estimated to be 1.6 percent and 4.1 percent, respectively [5].
The prevalence rates given in the European survey did not show uniform differences between eastern and western countries, as reported in Table 1.
Individuals over 65 years have higher prevalence rates of stroke, varying between 4.61 % and 7.33 %, as reported by international population-based studies [10].
The ILSA Italian study estimates that sex- and age-standardized prevalence rate of stroke is 6.5 percent (95% CI: 4.9 - 6.9) in persons aged from 65 to 84 years. Prevalence is higher

in men (7.4%; 95% CI:6.3 – 8.5) than in women (5.9%; 95% CI: 4.9 – 6.9) and increases with age, as showed in Table 3.

Age class (years)	Sex					
	Men		Women		Total	
	N	PR (95% CI)	N	PR (95% CI)	N	PR (95% CI)
65-69	579	5.7 (3.8-7.6)	571	2.8 (1.4-4.2)	1,150	4.1 (2.9-5.3)
70-74	602	7.0 (4.9-9.1)	539	6.3 (4.2-8.4)	1,141	6.6 (5.1-8.1)
75-79	568	9.2 (6.7-11.7)	543	7.4 (5.1-9.7)	1,111	8.1 (6.4-9.8)
80-84	554	10.3 (7.6-13.0)	537	10.2 (7.5-12.9)	1,091	10.3 (8.4-12.2)
Total	2,303	7.4 (6.3-8.5)	2,190	5.9 (4.9-6.9)	4,493	6.5 (5.8-7.2)

Table 3. Standardized prevalence rates (PR) for stroke and 95% confidence intervals (95% CI) in the age class 65-84 years, by sex. Italy, 2001 *(Source: Spread, 2005)*

2.1.4 Mortality of stroke

Stroke is the third most common cause of death in developed countries, exceeded only by coronary heart disease and cancer, accounting for 10% of all deaths (9% of all male deaths and 11% of all female deaths), that is about 400.000 deaths per year in the European Community countries. Stroke is the second leading cause of death above the age of 60 years [11] and the fifth leading cause in people aged 15 to 59 years old.
Stroke accounted for about one of every 16 deaths in the United States in 2004. About 50 percent of stroke deaths in 2003 occurred out of hospital. There was 150,147 (58,660 males, 91,487 females) stroke-related deaths in 2004 [5].
Figure 6 represents an international disease statistics on the death rates for total cardiovascular disease, coronary heart disease, stroke and total deaths in some countries in the world published by the American Heart Association in 2007.

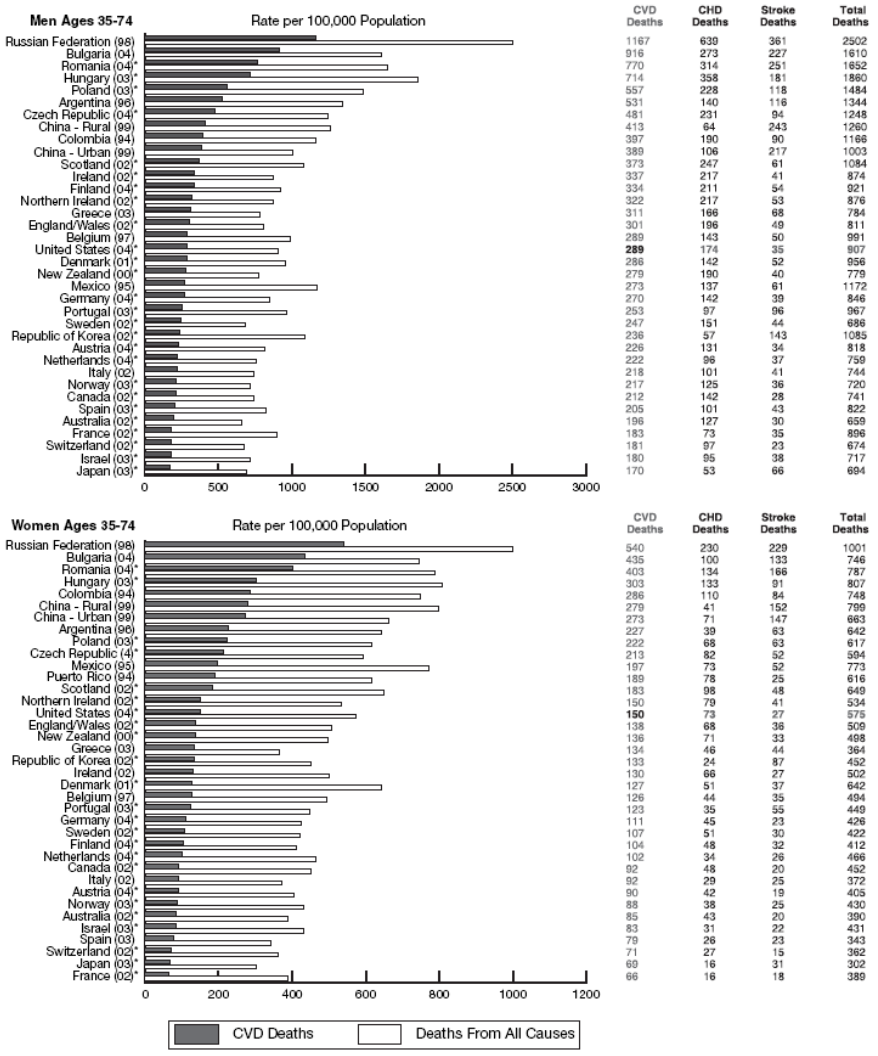

Figure 6. Deaths rates for Total Cardiovascular Disease, Coronary Heart Disease, Stroke and Total Deaths in Selected Countries, 2006 *(Source: American Heart Association, 2007)*

The period of highest risk is within the first 30 days, depending, in part, by stroke subtype. Almost 10% of subarachnoid haemorrhage patients die before hospitalization, with a very high fatality rate in the first two days. In contrast to cerebral infarction, where deaths begin to occur a few days to a few weeks, survival following SAH has increased over time, partly due to better diagnosis of less severe cases by using CT scanning and angiography [6].

The 1-year overall survival of stroke is roughly the same for men and women and has improved during the last years, thanks to a combination of factors, including a reduction in stroke severity at onset associated with increased detection of small, less severe strokes and better care of stroke patients.

Survival at 5 years is significantly better for transient ischemic attack than an ischemic stroke. According to that, the Rochester population-based study reported that 5-year survival for patients diagnosed with TIA is 66% as compared to 48% for those with ischemic stroke [12].

2.1.5 Risk factors of stroke

In addition to medical factors including previous TIA or stroke, ischemic heart disease, atrial fibrillation, the likelihood of having a favourable outcome decreased with increasing age.
Apart from biological traits such as age and sex, risk factors for stroke may refer to physiological characteristics such as high blood pressure, serum cholesterol, fibrinogen; behaviours such as smoking, diet, alcohol consumption, physical inactivity; social characteristics such as education, social class and ethnicity; and environmental factors that may be physical (temperature, altitude), geographical, or psychosocial.
At a population level, blood pressure and tobacco use are the two most important modifiable risk factors for stroke due to their strong associations, high prevalence and the possibility for intervention.
Epidemiological research has shown that risk of stroke rises steadily as blood pressure level rises 3-5 times with hypertension, and up to 8-fold, depending on the severity of hypertension [13]. Treatment with anti-hypertensive treatment has been suggested to reduce stroke risk by about 38 %.
Tobacco use increases the risk of ischemic stroke about two-fold and is furthermore also associated with a higher risk of hemorrhagic stroke [14]. There is a dose-response relationship so that heavy smokers (more than 40 cigarettes a day) are at a higher risk of stroke than light smokers (less than 10 cigarettes per day). Stroke risk decreases significantly two years after cessation of cigarette smoking and is at the level of non smokers by five years.

2.1.6 Disability of stroke

As well as producing a high mortality burden, cerebrovascular disease is the leading cause of disability in adults and each year millions of stroke survivors has to adapt to a life with restrictions in activities of daily living as a consequence of cerebrovascular disease. Many surviving stroke patients will often depend on other people's continuous support to survive.

One measure that takes account of both the burden due to deaths and disability for a particular disease is DALYs (Disability Adjusted Life Years), which is measured in days of potential life lost due to premature death and disability. The WHO Burden of Disease study uses DALYs to estimate the burden of disease. There were almost 50 million DALYs lost world-wide to stroke in 1999. This is almost 8.4 per 1,000 people, representing 3.5% of the total burden of all diseases. There is significant variation between regions in the total disease burden, from around 4.4 to 23.0 DALYs per 1,000, as showed in the Figure below [1].

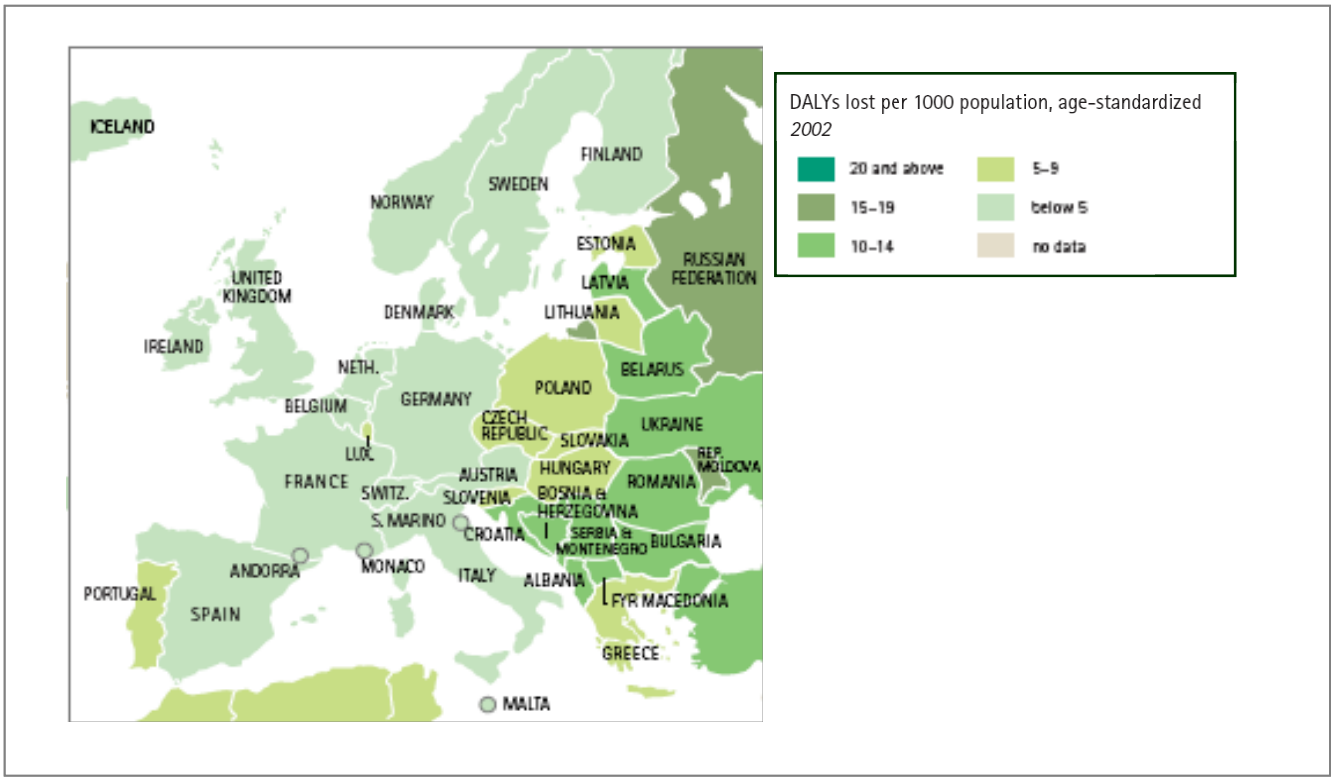

Figure 7. Healthy years of life lost to stroke, 2002 *(Source: WHO, 2002)*

In the Family Heart Study of National Heart Lung and Blood Institute [5], among ischemic stroke survivors who were at least 65 years old, these disabilities were observed at six months post stroke:

– 50 percent had some hemiparesis.
– 30 percent were unable to walk without some assistance.
– 26 percent were dependent in activities of daily living.
– 19 percent had aphasia.
– 35 percent had depressive symptoms.
– 26 percent were institutionalized in a nursing home.

2.1.7 Stroke Units

A significant improvement in acute stroke morbidity and mortality, could be achieved by the reorganisation of stroke care services with the goal of rapidly evaluating and treating acute stroke patients. Acute ward area with stroke-dedicated beds (at least 80% of admitted patients are stroke patients) and dedicated teams (at least one full-time physician and nurse were caring exclusively for acute stroke patients), the so-called Stroke Unit (SU), are implemented to face acute stroke patients.

Clinical trials and meta-analysis have consistently demonstrated the effectiveness of Stroke Unit (SU) services for hospitalised stroke patients, reducing the number of survivors who depend on others for support either at home or in a health care facility.

In the United States many hospitals do not have the necessary infrastructure and organisation for acute stroke care. In Ontario hospitals, a SU existed in only 4% of acute institutions [15].
The epidemiological East–West gap in European countries is not reflected by most quality indicators for acute stroke care (e.g. total number of acute stroke units available within each country) [7]. Most eastern European countries have a well-developed neurological care system for acute stroke but still have urgent technological and socio-economical needs. The leading role of clinical neurology in acute stroke care is visible in most but not all European countries.
In 2003/2004 a Stroke Unit survey was conducted in Italy by the Project on Stroke Services in Italy (PROSIT) [16]. In all 21 regions were counted 68 Stroke Unit and 745 General Ward. A conventional General Ward (GW) was a ward (neurology, internal medicine, cardiology or other) admitting stroke patients in the same wards with others patients and without dedicated beds and teams. Nationwide, only 9% of the hospital services has organised Stroke Unit care: the rates were lower in the central (10%) and southern (6%) regions than in the northern Italian regions (13%).
All regions except three had one Stroke Unit.

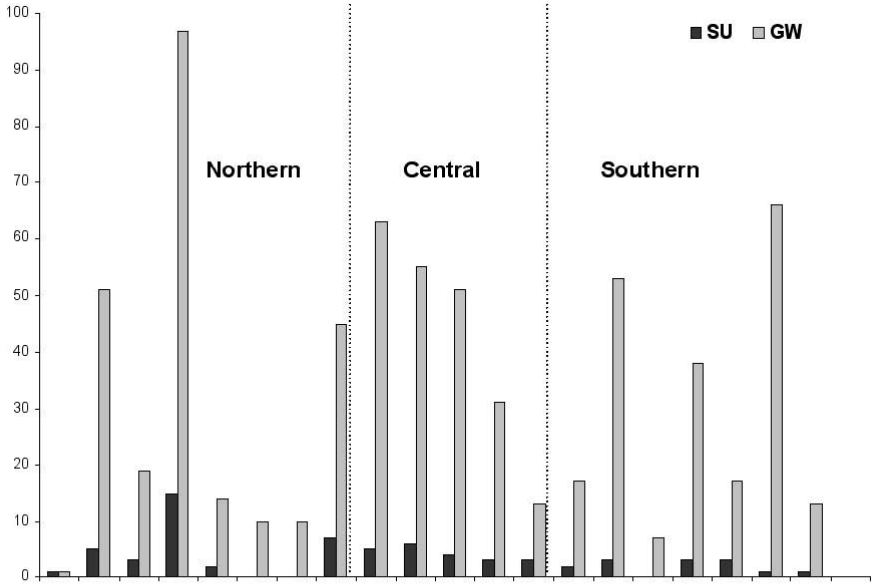

Figure 8. Number of stroke units (SU) and conventional general wards (GW) by regions, Italy 2004
(Source: Bersano A et al, Neurol Sci, 2006, 27)

The SU admitted more than 100 acute stroke patients per year, had more than one set of monitoring equipment per five beds, and about four full-time physicians and one physiotherapist per 20 patients.
The study shows the tendency in Italy to increase the number and the quality of structures dedicated to stroke care. Nevertheless, it demonstrated an overall shortage of stroke unit beds, also evident in many European countries where the percent of stroke patients hospitalised in a SU bed ranged from 5% to 40%. Stroke units have been shown to reduce both stroke morbidity and mortality by approximately 20% [17].
To determine whether admission to a stroke unit, rather than a conventional ward, affected the outcome of patients with acute stroke, an observational study was conducted in Italy between 2000 and 2004 [18]. Data were collected about 11,572 acute stroke patients hospitalised within 48 hours of the onset of symptoms either in a stroke unit (43%) or in a

conventional ward (57%). The study showed that there was an association between stroke-unit care provided in the acute phase of the disease and improvement of stroke outcome. In this setting, stroke-unit care could reduce in-hospital case fatality and also increase the proportion of patients living independently about 2 years after discharge, as showed in Figure 9.

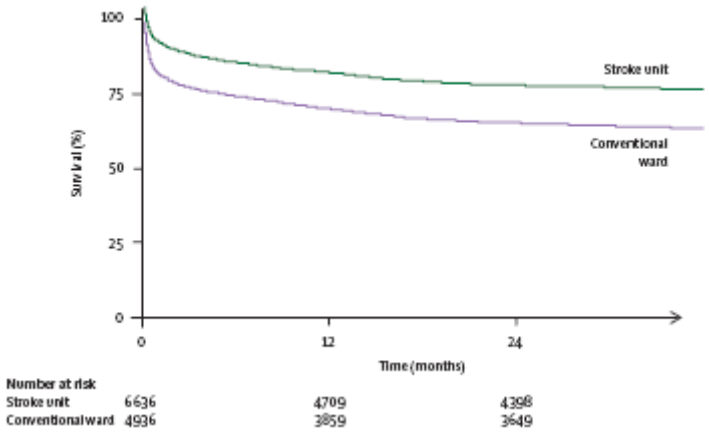

Figure 9. Survival curves for patients admitted to stroke unit or conventional ward, Italy 2004
(Source: Candelise L et al, Lancet, 2007, 27)

Provided admission occurs within 48 hours of onset, patients with acute stroke should be treated in stroke-unit wards with dedicated beds and staff, irrespective of age.

The expected number of new stroke events, based on the WHO stroke estimates and the United Nation's population projections, indicate that there will be an increase in the absolute number of stroke events from approximately 1.1 million per year in 2000 to 1.5 million per year in 2025, even with stable stroke incidence rates.
If the exposure to main modifiable risk factors of stroke would increase or be controlled, the estimated effect of slight increases or decreases in stroke incidence rates (±2% per 5 years), could lead to the difference by 2025 of ±150,000 stroke events when compared with stable rates [19].
These numbers strongly suggest for intensifying prevention of stroke, as improving stroke units for treatment and rehabilitative care.

2.2 Economic evaluation of stroke: a review

As described in the previous section, the healthcare of stroke has a significant medical, economic and social impact on health services.
Each year, in Europe, one million acute ischemic strokes are estimated to happen; who survives is left with serious functional disabilities [20].
Stroke is a disease that absorbs many economic resources in the diagnostic, therapeutic and rehabilitative phases.
The costs of stroke depend on casing mix, types of stroke care provided, age, gender and severity.
The healthcare of stroke involves many resources, as professionals, as institutional and non institutional facilities.
Usually, persons taking part to stroke patient management are: physicians, nurses, physiotherapists, occupational therapists, speech and language therapists, and general practitioners.
Inpatient management includes both acute care (i.e., hospital and rehabilitation centre) and long term care (i.e., nursing home) facilities; the outpatient care includes the various types of rehabilitation therapy and other healthcare services received by patients in a residential location, i.e., in a retirement home or at home.
The specific services included are emergency room visits, doctor visits, neurologist consultations, mental health visits, occupational therapies, physical therapies, speech therapies social worker visits, home nursing and home aids.

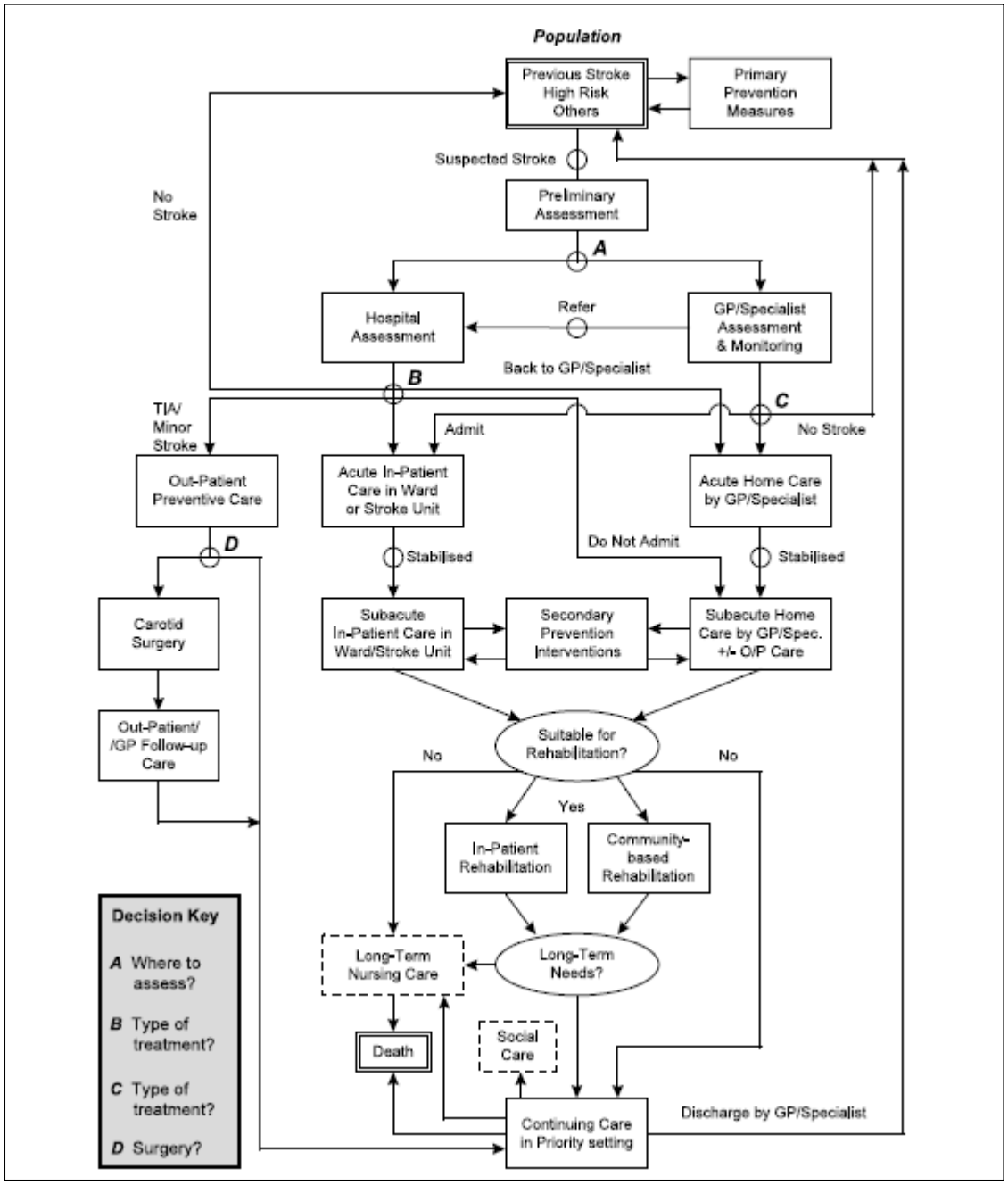

Figure 10. The stroke network *(Source: Sundberg et al., Health Policy 63, 2003)*

The goal of cost-identification analysis is to estimate the *absolute* cost associated with a medical problem (stroke, in our case). The findings from a cost-based evaluation could be used to assess whether a particular health problem is important (relative to other health problems) and deserving of increased research or public attention.

The most suitable technique for measuring the economic burden of stroke to society is the Cost-of-Illness approach. It was the first economic evaluation technique used in the health field and, at the core, it represents a descriptive economic method. The estimates provide information that describes the resources used and potential resources lost related to stroke.

Together with prevalence, incidence, morbidity, and mortality data, cost estimates help to portray the impact that society (or an organization) faces from stroke.

According to the Cost-of-Illness perspective, three categories of stroke- related costs may be identified:

- *Direct costs*: borne by the health care system, community and family in directly addressing the problem (e.g. hospital care, physicians services, nursing home care, drugs); they basically consist of goods and services provided for preventing, diagnosing and treating the stroke disease and the medical consequences of it as well as for the rehabilitation services. Direct costs also include the "out of pocket" expenditures incurred by patient and family.
  This category of costs is mainly influenced by the following factors:
  - the length of stay in hospital, that largely depends on the severity of stroke; - the death after stroke in hospital or needs for rehabilitation care and long term care. Saxena *et al.* reported that direct costs alone are about 70% of the total stroke costs, and these are largely determined by the length of stay [21].
- *Indirect costs*: they include non-medical societal costs such as productivity losses caused by the disease, borne by the individual, family, society and/or by the employer, such as short-term absence from work, early retirement or premature mortality.
- *Intangible costs*: usually the costs of pain, suffering, loss of leisure time loss of companionship and other non-financial impacts.

Sundberg [22] presents a model for estimating the cost of stroke in Sweden. He calculates that, in the baseline scenario, the most important cost component for stroke care is the continuing care such as long term nursing care, community-based care and social support services.

In figures, the cost of these services amounts to 68% of all stroke-related expenditure; acute and sub-acute care accounts for 12% of total costs and rehabilitation care for 17%.

Stroke Unit allows reducing risks of early mortality, continuing mortality and recurrent stroke; in the presented model, the costs of stroke care raises, due to the increased use of continuing care and rehabilitation services: a 10% increase in acute Stroke Units use raises overall costs by about 0.1%.

Moreover, better diagnosis and more appropriate treatments allows to reduced unknown strokes relatively more than other types of stroke; as a result, some deaths will be avoided and stroke disabilities in the population can be expected to increase.

As regards diagnostics, Sundberg affirms that if increased proportions of CT-scanning reduce mortality, diagnosing more over the unknown cases as ischemic stroke, at the same time, costs increase; most of the increase is due to additional rehabilitation and sub-acute stroke care.

Truelsen discusses a summary of selected studies on costs per patient in some European countries.

STUDIES	COUNTRY	COST CATEGORIES	SAMPLE SIZE	COSTS PER PATIENT ADJUSTED 2004 EUR[§]
Carod-Artal *et al.* 1999	Spain	Direct medical costs	118 patients	€5,435 during the 1st year
Ghatnekar *et al.* 2004	Sweden	Direct and indirect costs	4357 patients from Risks Stroke, a nationwide register	€13,903 in direct costs during the 1st year
Grieve *et al.* 2000	UK	Direct costs	328 patients from the South London Stroke Register	€7,393 during the 1st year
Porsdal & Boysen 1999	Denmark	Direct medical and non-medical costs	475 patients with intracerebral hemorrhage (90), cerebral infarct or unspecified stroke (385)	€9,815 during the 1st year
Spieler *et al.* 2002	France	Direct medical costs	494 consecutive patients	€20,114 over 18 months
Van Exel *et al.* 2003	Netherlands	Direct medical and non-medical costs	598 consecutive patients	€16,048 over 6 months
Weimar *et al.* 2003	Germany	Direct and indirect costs	586 patients	€20,239 over 1 year
Andersson *et al.* 2002	Sweden	Inpatient costs and social services	121 patients	€26,557 during the 1st year
Bergman *et al.* 1995	Netherlands	Lifetime direct costs	24.007 patients	€33,604 for women; €28,716 for men
Claesson *et al.* 2000	Sweden	Direct medical and non-medical costs	249 consecutive patients	About €25,493 during the 1st year
Dodel *et al.* 2004	Germany	Direct medical and non-medical costs	340 consecutive patients admitted for stroke (or TIA)	€3515 for ischemic stroke and €5131 for intracerebral hemorrhage (per admission)
Levy *et al.* 2003	France	Direct medical costs	Model + stroke pop. From CAPRIE trial	€6250 over 2 years
Patel *et al.* 2004	UK	Direct medical and non-medical costs	447 acute stroke patients randomly assigned to stroke unit, stroke team, or domiciliary stroke care	First year costs: €16,403 for stroke unit, €13,648 for stroke team, and €9,799 for domiciliary stroke care
Terent *et al.* 1994	Sweden	Direct and indirect costs	162 +1 25 patients in two populations	€26,043 during the 1st year and €20,715 during the 2nd in the first population (N=162). Slightly lower in the second pop.
Zethraeus *et al.* 1999	Sweden	Direct medical and non-medical costs	25 consecutive patients	€23,666 during the 1st year

Table 4. A summary of selected studies on costs per patient in some European countries*(Source: Truelsen et al. European Journal of Neurology 2006)*
[§] *EUR STAT, 2004A; EUROSTAT, 2004B; EUROPEAN CENTRAL BANK, 2004*

Grieve, in his study, compares the costs of acute stroke across Europe identifying several categories of stroke costs:

1. initial acute hospital stay: the duration of stay in hospital is very variable and depends on the portion of patients transferred to a rehabilitation unit;
2. rehabilitation unit stay;
3. community costs;

4. ambulatory costs.

The costs of acute stroke vary in each European countries and the differences may be explained by the model of care adopted: the duration on stay in hospital; daily input from therapists; the use of investigations; daily availability of doctors; the costs of employing health care professionals, that are very different comparing country to country (in Eastern Europe, for ezample, they are much lower than in Western Europe).
The length of stay is a very important cost factor, as it absorbs many economic resources: a large percentage on health care system's expenditure is represented by hospital care delivery and the majority of the expenditure is due to the staff costs and hospital expenses.
The OECD working paper's underlines the relationship between the length of stay and hospital fatality rates: the increasing length of stay being associated with lower fatality rates.
The Figure shows the trends in mean length in hospital for stroke patients in some countries.

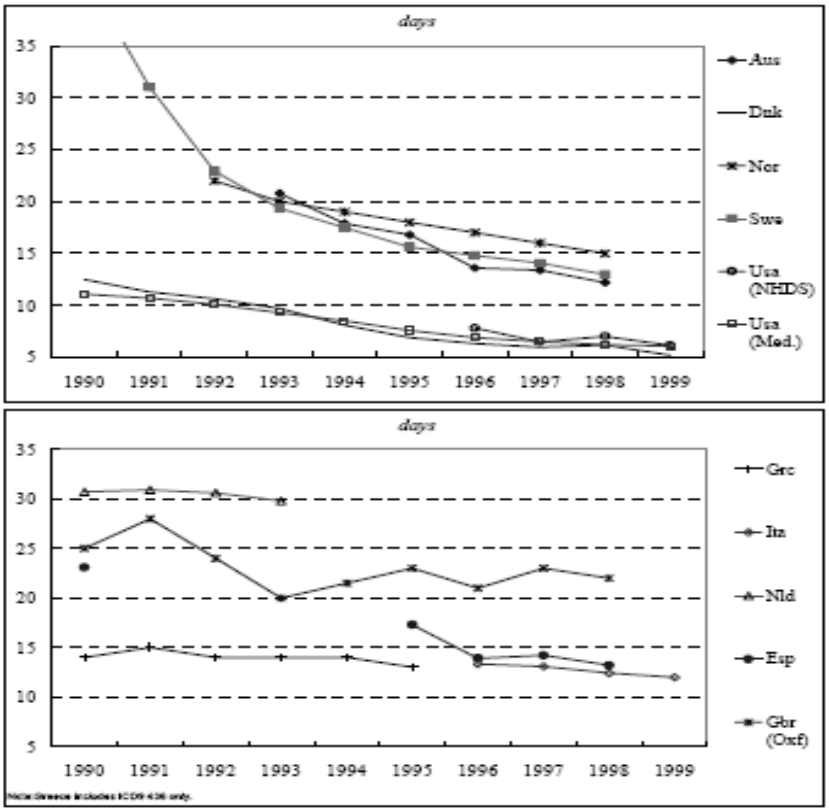

Figure 11: Trends in the mean length in hospital for stroke patients
(source: OECD, DELSA/ELSA/WD/HEA, 2003, 5)

As regards to organizing features, the patients are hospitalized in Stroke Unit, in General ward or in Neurology, where costs are different.
The Stroke Units are unit care with 4-6 beds and a multidisciplinary équipe with specialists, nurses and physiotherapists dedicated to cerebrovascular patients [8].
An Italian study shows that the length of stay in a Stroke Unit is more expensive than staying in a General Ward or Neurology due to an higher intensity of medical treatments, whereas mortality, disability and rehabilitative phase costs are reduced [23].
The Figure below shows the length of stay (LOS) and the proportion of patients admitted to Stroke Unit in 13 countries analyzed in the study of J. Jaime Caro *et al.* [24] where 70% of

costs regards the initial hospitalization. The total costs changing is due to the age of patient, comorbidity and severity of disease.

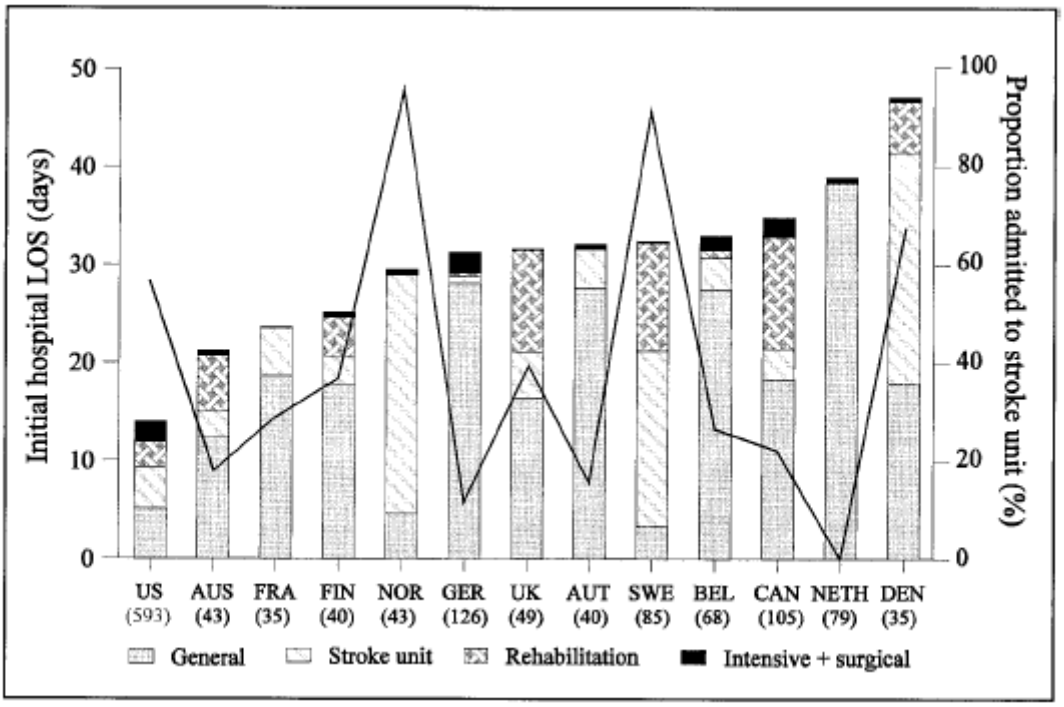

Figure 12. Initial hospital LOS by ward type (left *y* axis) and proportion of patients admitted to a stroke unit (right *y* axis) in the 13 participating countries. *(Source: Caro et al., Stroke 2000, 31) The number of patients in each country is provided in parentheses beneath the x axis.*

The study of Launois *et al.* [25] analyses the clinical and economic benefits of stroke unit compared with conventional care, in France. Annually, there occur between 120,000 and 150,000 strokes and six-month mortality rates are between 30% and 45%.
Three are the units types: acute units, caring for patients for 7 days after stroke, rehabilitation units, which admitted patients afterwards and integrated stroke units, which identify these functions simultaneously.

The Table below indicates the cost per patient in different ward according to health state.

	Conventional Care		Stroke Units	
Health State	€	%	€	%
Hospitalization	4 177.41	13.6	4 267.81	12.3
Minor disability	14 149.56	45.6	17 254.03	49.8
Intermediate disability	5 251.56	16.9	4 977.61	14.4
Severe disability	7 404.75	25.9	8 138.64	23.5
Total cost	30 983.28		34 638.09	
Difference in cost, €	3 654.81			
Efficacy*	8.28		10.97	
Difference in efficacy	2.69			
Incremental cost-effectiveness, €	1 359.42			

*Efficacy is measured as the total number of trimesters spent in minor disability, including corrections for half-cycles.

Table 5: Cost per patient and per health state over 5 years and cost-effectiveness *(Source: Launois et al., Stroke 2004, 35)*

The total costs per patient are € 30,983.28 for a conventional care unit and € 34,683.09 for stroke unit but the treatment in stroke units provide a benefit of 2.69 trimesters of survival without disability over 5 years.
In general, the expenditure for conventional care of the 120,000 new strokes a year would be 3,718 million € over 5 years, for stroke units is about 4,156 million €.
The Figure shows the total cost for 120,000 stroke patients share among the ward care.

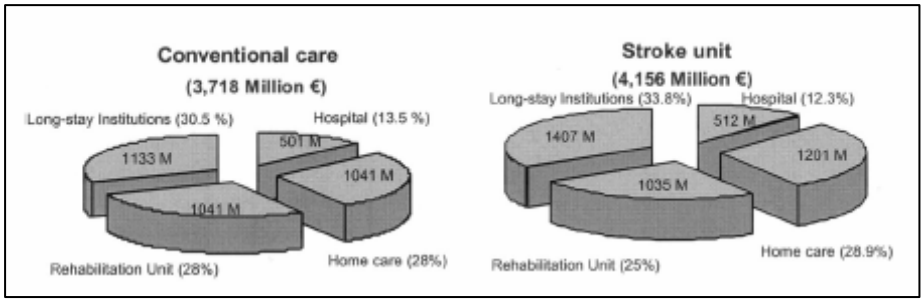

Figure13. Total cost for 120,000 stroke patients per year over 5 years in conventional care and stroke units *(Source: Launois et al., Stroke 2004, 35)*

In The Netherlands, Job van Exel [26] has investigated the cost of stroke focusing on stay in hospital and on the treatment of stroke. Generally, the wait for discharge is too long than the real need for medical treatments, so about 10 of the average 28 days to stay in hospital after stroke are estimated to have no medical reasons. Consequently, many "blocked beds" cannot be used for new patients needing acute treatment.
The health care of stroke is going in the direction of a disease management in terms of "stroke service". A "stroke service" can be defined as "a regional chain of caregivers: medical, nursing and therapy staff, who together, as a network, warrant integrated expert and coherent treatment and care for stroke patients in all phases: acute, rehabilitation and chronic of the ailment".

The purpose of "stroke service" is to give *the right care at the right time in the right place from the right professional.*
The authors identify as stroke costs:
- *Hospital costs*: accommodation costs, medication costs, assessment, medical and paramedical treatments. The length of stay in hospital depends on the severity of stroke, the death in the acute phase, the waiting lists for nursing home care.
- *Nursing home costs:* his principal component is the accommodation costs.
- *Rehabilitation centres costs*: the primary are accommodation costs.
- *Patients who stay at home*: home care, paramedical care, GP visit, cost of medication, home adaptations and assistive devices.

Analyzing the direct costs during the first 6 months after hospital admission, after stroke patient costs depend on the level of disability, and on predisposing (age, gender, place of residence/having a partner) and enabling (waiting days and waiting lists) factors.
As regards to disability, the cost of institution care (hospital, rehabilitation centre and nursing home) grows with the degree of disability; specially for ambulatory care, patients with mild and moderate disability are the most expensive. In case of single persons before the stroke, it seems to be mainly costly because of the probability of being admitted in nursing home is high.
Then again, managing care factors may improve cost-efficiency of care for stroke patients, reducing waiting lists for nursing home and home care and for this way discharging patients from expensive hospital beds.

Died within 6 months?		Disability[a]					Average
		Independent (n = 31)	Mild (n = 81)	Moderate (n = 98)	Severe (n = 126)	Very severe (n = 259)	
Yes	Total costs	4,510	5,630	10,020	10,240	7,500	7,870
	- institutional	3,720	4,300	9,200	9,310	7,440	7,630
	- non institutional	790	1,330	820	920	60	240
No	Total costs	6,610	6,860	13,170	23,810	30,610	19,160
	- institutional	4,350	3,810	9,290	20,840	28,860	16,380
	- non institutional	2,260	3,050	3,880	2,960	1,750	2,780
Total	Total costs	6,470	6,800	12,950	21,440	18,210	15,860
	- institutional	4,310	3,830	9,290	18,830	17,360	13,820
	- non institutional	2,160	2,970	3,660	2,610	840	2,040

[a] Based on Barthel Index. Categorisation: BI of 20 independent; BI of 15–19 mild; BI of 10–14 moderate; BI of 5–9 severe; BI of 0–4 very severe

Table 6: Average total costs per patient by disability at hospital admission and mortality status after 6 months (in € of 1999; N = 595)
(Source: Job van Exel et al. Cost Effectiveness and Resource Allocation, 2003, 1)

The Grieve' s study [27] compares the costs and survival of hospitalized stroke patients from 13 European centres. The analysis about mean total costs in 3 months after stroke in each centre is very interesting.

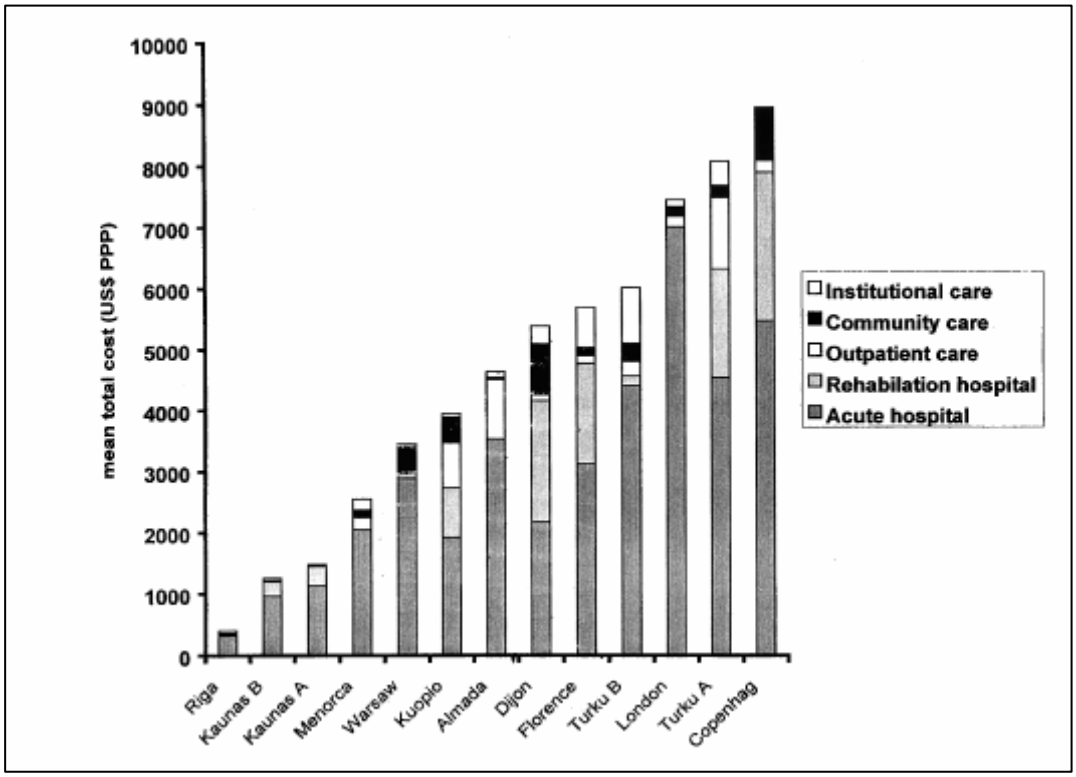

Figure 14. Mean total costs in 3 months after stroke in each centre (US$/PPP)
(Source: Grieve et al, Stroke, 2001, 32)

Variations in the lengths of hospital stay have an high impact in mean total costs: centres with average stay over 30 days have also the highest costs. In some centres the costs of outpatient care and community care are significant.
The authors affirm that the mean total costs of care varied between the centres because of differences in the unit costs and the resources used.

In the United States the cost of cardiovascular diseases and stroke for 2007 is estimated at $431,8 billion. The direct and indirect cost of stroke is $62,7 billion.
The mean lifetime cost of ischemic stroke is estimated at $140,048 and includes inpatient care, rehabilitation, and follow-up care essential for lasting deficits.
In a population study of stroke costs within 30 days of an acute event, the average cost was $13,019 for mild ischemic strokes and $20,346 for severe ischemic strokes (4 or 5 on the Rankin Disability Scale).
Taylor *et al.* affirm that the inpatient hospital costs for an acute stroke event account for 70% of first-year post stroke costs [28].
Diringer *et al.* assert that the largest components of acute-care costs were room charges (50%), medical management (21%), and diagnostic costs (19%) [29].
Demographic variables (age, sex, and insurance status) are not associated with stroke cost. Severe strokes cost twice as much as mild strokes.
The Table shows the estimated direct costs and indirect costs of cardiovascular disease and stroke.

	Heart Diseases	Coronary Heart Disease	Stroke	Hypertensive Disease	Heart Failure	Total Cardiovascular Disease
Direct Costs						
Hospital	$94,2	$48,4	**$17,9**	$7,2	$17,8	$133,0
Nursing home	$22,0	$11,6	**$15,2**	$4,5	$4,2	$45,3
Physicians/other professionals	$22,2	$12,5	**$3,5**	$12,5	$2,3	$43,3
Drugs/other						
- Medical durables	$20,0	$9,2	**$1,2**	$23,0	$3,0	$47,2
- Home health care	$6,4	$1,9	**$3,8**	$2,1	$2,9	$14,4
Total expenditures	**$164,9**	**$83,6**	**$41,6**	**$49,3**	**$30,2**	**$283,2**
Indirect costs						
Lost productivity/morbidity	$22,3	$9,8	**$6,5**	$7,8	N/A	$36,3
Lost productivity/mortality	$89,9	$58,2	**$14,6**	$9,3	$3,0	$112,3
Grand totals	**$277,1**	**$151,6**	**$62,7**	**$66,4**	**$33,2**	**$431,8**

Table 7. Estimated Direct and Indirect Costs (in Billions of Dollars) of Cardiovascular Disease and Stroke – 2007 *(Source: American Heart Association, 2007)*

The Figure below shows the estimated direct and indirect costs of major cardiovascular diseases and stroke.

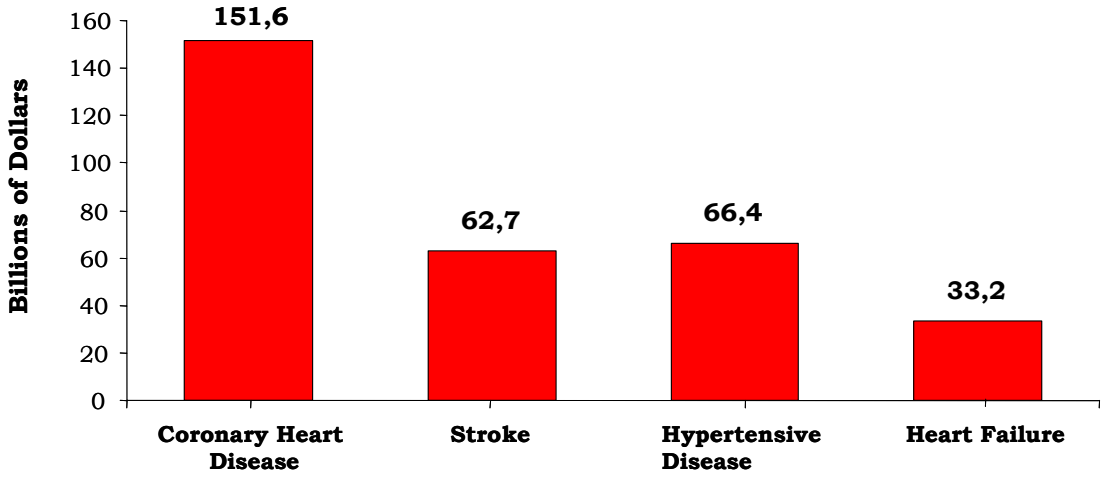

Figure 15. Estimated direct and indirect costs of major cardiovascular disease and stroke *(Source: NHBLI)*

Rehabilitative therapy is an important component of the stroke treatment and accounts for 16% of the total 6 months of stroke care costs [21].
The need for rehabilitation services is expected to increase due to two factors: first, there is a decrease in age standardized mortality rate of stroke patients; second, there is an increase in the ageing population in development nations.

A Swedish study [30] compares home-based and inpatient rehabilitation versus hospital-based rehabilitation, during the period 1996-1998.
Comparing to realities, coming out that the number of treatment hours with physiotherapy and occupational therapy is significantly greater in the home-based rehabilitation during the acute care ward stay; on the contrary, the number of treatment hours spent with physicians and nurses is significantly greater in the hospital-based during rehabilitation, and these gaps may depend on organizational differences.
We can conclude that stroke is a very expensive disease both in terms of financial resources and in terms of social impact on Community.
The management of a stroke patient requires high expert medical treatments, in specific health facilities, provided by a multidisciplinary *équipe* during all steps of stroke patient's treatment course.

Some studies evidence as:

1. Stroke Units are more expensive than traditional wards (i.e. General and Neurology wards), but having better results in terms of efficacy and cost- effectiveness;

2. the length of stay in hospital is the higher component of direct cost in stroke health care; it depends on: lower risk of mortality, different degree of stroke severity and length of waiting lists for nursing homes;

3. disability due to a stroke event is a crucial financial factor as regards to the dimension of increasing problem, the severity of disability degree and the sustainable of overall spending.

3 An outline of the Alladin ADD

ALLADIN is an innovative platform for whole-body isometric force measurements to be used in neuro-rehabilitation for assessing post-stroke functional recovery. The platform consists of an ergonomic mechanical structure, embedding eight force/torque (F/T) sensors, that sample data about the performance of simulated activities of daily living (ADL) in stroke patients. The overall Alladin system also includes a dedicated database, where all measures and other clinical scores are stored, and a PDA-based natural language system interface for the therapist.

The system aims at offering an innovative method for decision support in neuro-rehabilitation. It calculates and predicts the functional recovery of stroke patients and makes clinical assessments and quantitative measurements easily exchangeable among clinical stroke rehabilitation units.

The basic assumption inspiring this research work is that imagination and initiation of the task have the same functional properties as performing the task. That is why the platform uses an isometric approach for post-stroke functional assessment.

The device explores the sensory motor reorganization after stroke by evaluating six different ADL: drinking a glass of water, picking up a spoon, turning a key, lifting a bag, reaching for a bottle and bringing a bottle to the opposite side.

The whole platform consists of a control and data acquisition workstation, a transit lying wheelchair, a monitor for the patient, trunk device, seat device, arm device, finger device, foot device, frame and accessory storage board (see Figure.16).

The eight 6-axis F/T sensors are installed behind the trunk, below the posterior, at the affected lower arm, at the affected thumb, index and middle finger, at the affected foot and toe.

The platform has three positional settings for the patients according to the tasks to be performed. The first operational position is associated to the “drinking”, “turning the key” and “picking up a spoon” tasks. A second position is selected for the “lifting the bag” task and a third for the “reaching for a bottle” and “bringing a bottle to the opposite side” tasks. All operating instructions are presented on a screen in front of the patient. A first instruction is the video presentation of the task to be initiated by the patient; the second instruction is an invitation to “memorize” the task and then to “execute” it. The measured behaviour is the combined output of the 48 channel, representing the x, y, z F/T data for all the F/T sensors [31].

Figure 16. The three ALLADIN platforms used for clinical trials in Gent, Dublin and Budapest

The ALLADIN project aims at giving a contribution to the evolution in stroke rehabilitation. It aims at developing a standard procedure in assessing the functional recovery outcome in neuro-rehabilitation, in order to support the clinical decision making towards the choice of the best rehabilitative process for each patient. Moreover, it aims at giving quantitative measures for assessing functional recovery, to be compared with the qualitative methods at present employed in the clinical practice (e.g. evaluation scales). Such methods, in fact, are not so specific and fine to classify each patient based on his/her grade of severity; on the contrary, patients assessed with qualitative scales are often grouped together according to very broad categories of stroke severity. With the description through the natural language a more detailed description and classification of each patient can be performed.

4 A SWOT analysis of the Alladin system

4.1 Methodology

A SWOT questionnaire has been proposed to each partner of the ALLADIN project, both clinical and technical. The SWOT analysis is a standard method for evaluating a system, for identifying its Strengths and Weaknesses, and for examining the Opportunities and the Threats, that are possible aspects to be improved or exploited in a future perspective.
The scheme of the designed and submitted questionnaire is shown below:

ALLADIN SWOT ANALYSIS

Each Alladin partner should fill in this table by listing and shortly justifying what he considers *strengths, weaknesses, opportunities* and *threats* of Alladin, according to his own perspective. That is, clinical partner will think over SWOT from a clinical point of view and the technicians from a technical point of view

The required information is grouped into two main categories:
Internal factors: the *strengths* and *weakness* of the technology itself, if compared with the state of the art or other clinical/technical choices.
External factors: the *opportunities* and *threats* presented by the external environment.

A further required effort is to try to find an answer to the following questions:

1. How can we use each Strength?
2. How can we stop each Weakness?
3. How can we exploit each Opportunity?
4. How can we defend/destroy against each Threat?

After receiving the required information by each partner, the teams of SSSA and UCBM will aggregate the data so that possible scenarios for Alladin will be analyzed taking into consideration:

- the technical perspective
- the clinical perspective
- the economic perspective

INTERNAL	Strengths	
	Weaknesses	

EXTERNAL	Opportunities	
	Threats	

1. How can we use each *Strength*?
2. How can we stop each *Weakness*?
3. How can we exploit each *Opportunity*?
4. How can we defend/destroy against each *Threat*?

The questionnaire was sent by e-mail to all the ten partners to be filled in: nine filled questionnaires were received for results analysis (90% responding ratio). The results were collected, and all the answers concerning similar aspects were grouped together. A schematic presentation of results is provided in the following paragraph.

4.2 Presentation of the results

The total number of Strengths, Weaknesses, Opportunities and Threats listed by each partner in the first part of the SWOT questionnaire is presented below.

Tot answers: **130**
Tot. Strengths: **47**
Tot. Weaknesses: **40**
Tot. Opportunities: **25**
Tot. Threats: **18**

Each answer can be grouped as belonging to a 'category'. All the categories are listed below, and the number of answers for each category is highlighted in brackets.

Strengths

1. Robust, bringing few technical problems during clinical trials, easy to maintain and reliable in interaction with patients. **(8 answers)**
2. Easy to use and setup, with a simple entry of the patient. Usable by hospital staff without requiring technical support (useful user manual translated in several languages. Its modularity allows for the use of independent devices. **(7 answers)**
3. STM tool is reliable, easy to use and set up (e.g. no need of training sessions for speech recognition). **(6 answers)**

4. Use of natural language helps therapists in describing patient's conditions in a detailed way ('fine granularity of the ALLADIN ontology'). **(5 answers)**
5. It gives quantitative measurements for assessment: possibility for standardized and easy-interpretation outcome measurements scales. **(5 answers)**
6. Multichannel and multi-task analysis gives large amount of data and information on different sensor activation patterns. **(5 answers)**
7. Assessment through functional tasks (ADL) and by using real objects seems to have positive impact on patients. **(4 answers)**
8. Functional assessment is possible for patients in early phase of stroke. **(2 answers)**
9. ADD can be used in integrated scenarios, which include other instruments or brain imaging techniques. **(2 answers)**
10. Others **(3 answers)**

Weaknesses

1. Weak reliability/weak validity. Faulty/incorrect use of the system is possible, especially in F/T recording phase. Wasting of data is possible. Difficulty in estimating the onset of movement. **(10 answers)**
2. Lack of feedback for the patient. **(5 answers)**
3. Limited entry of clinical data using natural language (and also no automatic update of the ontology). **(5 answers)**
4. Some working problems with the PDA's software, especially for initial settings and updating. **(4 answers)**
5. Interpretation of a large amount of different kinds of data (e.g. F/T measurements, NL descriptions, clinical scales) is somehow difficult. **(3 answers)**
6. Limited compliance with the anatomical variation of the patients. Some imprecision in fixing some patients to the device. **(3 answers)**
7. Large footprint, lack of portability of the equipment (lots of cables). **(3 answers)**
8. Limitation in the models for data mining. **(2 answers)**
9. Difficult integration to HIS. **(1 answer)**
10. Others **(4 answers)**

Opportunities

1. The assessment of different body parts, the data stored in the Data-Base, and the whole Alladin technology/approach can be used in other clinical investigations/biomedical applications (i.e. not only in stroke recovery). **(11 answers)**
2. The device so far developed can act as a starting point for technological improvements and refining (e.g. in the ontology management system) or new technologies addition(e.g biosensors). **(5 answers)**
3. The STM tool can be used for entrying scales templates, or in other applications. **(2 answers)**
4. From the 'economic' point of view the ADD can be useful for giving indications on the importance, duration and outcome of rehabilitation. **(2 answers)**
5. Validation and definition of novel quantitative assessment protocols in neurorehabilitation through further studies. **(2 answers)**
6. The use of ADL tasks to assess the recovery has been adopted in previous researches: the results coming from the ADD can be easily accepted. **(1 answer)**
7. Others **(2 answers)**

Threats

1. Acceptance of Alladin technology among physiotherapists, medical doctors and patients. **(7 answers)**
2. Need of longer validation procedures, in order to obtain a form of the device that can be employed in the everyday clinical practice (possibly with certification), and in order to successfully integrate the ACSS in each HIS. An improvement in the STM has to be considered in order not to limit the physiotherapist's language. **(6 answers)**
3. Diffusion of other robotic systems, or brain imaging technologies or low cost systems that can provide alternative solutions for quantitative functional assessment and for identifying markers for functional recovery process. **(3 answers)**
4. Lack of biofeedback, in presence of other biomedical devices that have this function. **(2 answers)**

In the second part of the questionnaire it has been asked to the partner to list some ideas on how to use, reduce, exploit and destroy each strength, weakness, opportunity and threat. The most recurring answers are shortly listed below.

Possible use of strengths

- Disseminating results.
- Further experimental studies.
- Using the same approach in other similar scientific domains.
- Disseminating the Alladin approach among medical users, patients and, in general, to the scientific community.

Possible reduction of weaknesses

Wide interest in going on with the validation of the Alladin approach. Keeping the costs as low as possible, major efforts seem devoted to improve:

  - flexibility of Alladin hardware (e.g. fitting of patients, but also reducing the bulk),
  - flexibility of Alladin classification software,
- Data analysis and interpretation to be performed yet.

Possible exploitation of opportunities

- Sharing project results with the whole rehabilitation community, in order to show all the advantages.
- Use the Alladin approach, technology and data in other clinical investigations.
- Contribute and define standard clinical protocols for neurorehabilitation, starting from the results of the Alladin clinical trials.

Possible solutions to the threats

- Implementing biofeedback.
- Combining data mining outcomes with clinical experts experience in data analysis to optimize interpretation of data.

4.3 Discussion of results

As a result of the questionnaire survey which was distributed among all the project partners, an overall acceptance of the ALLADIN approach can be envisaged, together with a common idea that is worth going on with the validation procedures of the ALLADIN technology and with clinical trials, in order to collect results to be shared among other groups as soon as possible.
Anyway, some technical limitations of the ALLADIN platform appear plain to almost all the partners, especially the clinical ones, that experienced both ALLADIN limitations and advantages in their everyday clinical trials.
Lots of internal strengths have been indicated, while a smaller number of weaknesses has been found. The same can be said as regards the opportunities and the threats.
The majority of the expressed strengths concerns the easiness of use and robustness of the ALLADIN hardware and the use of natural language for describing patients' conditions.
Many ideas have been proposed on how to use strengths and exploit opportunities. As an example, the most cited opportunity is the possibility of having many data coming from different body districts, that can be exploited by using them in other clinical investigations or by sharing them among other groups.
Suggestions have been given on how to reduce weaknesses, especially from the technical point of view concerning the ALLADIN hardware.
Several doubts have been expressed on the difficulty in the interpretation of the large amount of data collected during the trials, and suggestions about the development of an effective data mining to be combined with traditional clinical data analysis from experts have been made.
One important point that has emerged is the need for implementation of a sort of biofeedback for the patient. This is to overcome a threat coming from other existing robotic and mechatronic technologies that already implement such functionality and give such information.
All the proposed efforts are devoted to the definition of a standard procedure for the assessment of functional recovery after stroke, that can provide quantitative data for interpretation of patients' conditions, that is useful for decision making in terms of the right choice of the rehabilitative process of each patient.

5 An operative tool for the assessment of the Alladin ADD costs and cost-savings

For the purpose of investigating and verifying how the diagnostic and rehabilitative route for the management of stroke patient could change after the implementation of Alladin methodology, a questionnaire was designed.
The questionnaire aim to assess the diagnostic phase and the rehabilitative one according to the level of severity for stroke, comparing the traditional method with Alladin.
The diagnostic stage refers to patient's condition soon after the stroke event, while the assessment phase relates to the rehabilitation treatment. We decided to leave out the therapeutic phase, since it mainly involves pharmacologic treatments.
The main aim is to examine all the services provided and the human resources involved in the process, comparing the traditional techniques with the Alladin device. Particular attention is given to the analysis of the time spent for services providing an estimation of direct costs of the two methods and related cost savings.
The questionnaire considers three levels of severity for stroke: *mild*, *moderate*, *severe*/*very severe*. In order to avoid too much data dispersion, we decided to join together the "very severe" class with the "severe" class.
Checking the box corresponding to qualitative items, records allow to compare diagnostic tools of traditional method with Alladin.
Information related to healthcare and professionals involved in diagnostic and rehabilitative phases are requested with open ended questions specifying type and corresponding number of services, professional skills, number of professionals involved and mean time spent for services provided (see Appendix).
A pilot questionnaire was pre-tested by sending it to clinical partners in order to improve his validity. It was asked to TCD, NIMR and AHS for provide feedbacks in order to revise the questionnaire and define a final questionnaire that could be be submitted for collecting data, analysing and estimating costs.

6 The proposed theoretical/methodological approach

A theoretical model is proposed in this section with the aim to support the cost-saving related to the use of the Alladin ADD – once at the best running – for the clinical assessment of stroke patients.

A traditional approach is compared to the Alladin one, considering the diagnostic and the rehabilitative steps of the assistive route for a stroke patient. Both approaches are graphically represented and summarised in the following Figure:

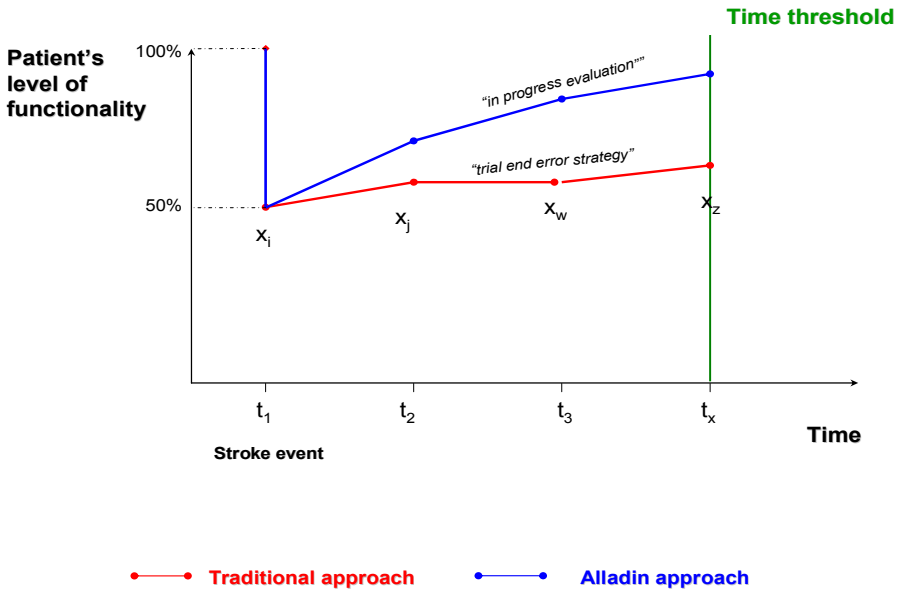

Figure 17. The methodological approach to Alladin
(Source: our elaboration)

Supposing the stroke occurred at t_1, a loss of functionality, hypothesized to be approximately 50%, happens in the same time.
It is well established from the medical literature that the first months after the stroke are extremely important in terms of recovering functionality. During this period, patient's recovery, if any, will be periodically assessed using evaluation scales, as consequence of x_i , x_z therapeutic strategies established at every t_j, $j=1...x$. After the t_x month threshold, rehabilitative therapies get quite no incremental effects.
Moving along a "trial and error strategy" that is the one adopted until the most effective treatment, if any, is identified, further adjustments may be introduced in the settled therapy: from x_j to x_w and from x_w to x_z up to t_x time that is the time limit fixed in the model after the stroke event.
In this example, according to the model, the "trial and error strategy" produces very low incremental improvement in the functionality recovery of stroke patient; in the proposed example, in fact, the recovery is about 15% (from 50% level of functionality after stroke to 65% after treatment) for the therapeutic strategy x_i and about 5% (reaching the final level of 70% after treatment at time t_x) for the therapeutic strategy x_w at time t_x, *passing through the substantially not effecting therapeutic strategy* x_j.
The main advantage of the Alladin approach is to allow a precise assessment of both the severity of stroke and the level of lost functionality at t_1 time, as long as an evaluation of the expected return from different potential therapeutic strategies, so:

- reducing the uncertainty in the definition of the right therapy,
- allowing early and timely adjustments in the treatment strategy in a kind of "fine tuning" process,
- allowing estimation of the expected level of recovery related to the x_i therapeutic strategy,
- selecting the most promising one among the x options.

At the core, the final advantage of the "in progress evaluation" of the functional recovery on which the Alladin approach is based, is to allow early readjustments in the therapeutic strategy in order to identify timely – and within the x months time limit (the most valuable months) – the most efficacious treatment. *The expected result is a higher level of recovered functionality*.
It is worth to underline the strong implications of the Alladin approach in terms of healthcare – and social – costs and cost-savings.
Cost -savings rise mainly from the following elements:

- an early selection of the most promising therapeutic strategy basing on the reduction of uncertainty ("trial and error" implies costs and new costs…);
- a reduced number of changes in the therapeutic approach;
- an higher final level of recovered functionality (that is minimization of residual disability);
- a better understanding of the time when to suspend or reduce the therapies because no/or very limited incremental benefits may be expected (the judgment about the prosecution of inefficacious treatments depends on ethical criteria, financial resources available, or on possible psychological positive effects of the therapy (placebo effect); in any case, this choice pertains to the health care political sphere.

Cost savings refer to both public and private resources saved mainly as a consequence of a lower level of final residual disability. Applying again the Cost-of-Illness approach, considerable social cost-savings, measured in direct, indirect and intangible costs, come from reducing the residual disability of the stroke patient.

According to forensic medical studies [32, 51, 52, 53], the relationship between the level of disability and its implications on the patience's life is not a linear one. In particular, it has been demonstrated that there is an exponential relationship: as the level of disability increases, the negative implications on the patience's life are higher and higher. A decline of conditions in a person with a severe level of disability has a more negative impact on his/her life conditions than may have the same decline effect on a person with a mild level of disability. The negative impact, in terms of marginal damage, increases as the patient level of disability increases [54, 55, 56, 57].
If we consider that the costs of taking care of a disabled person grow in accordance to the negative effects on life conditions due to the disability decline, we can assert that the usefulness of ALLADIN (that is expected to allow the reaching of a higher final level of functionality recovered) in terms of socio-economic savings increases as the level of disability increases (this relationship is graphically represented below).

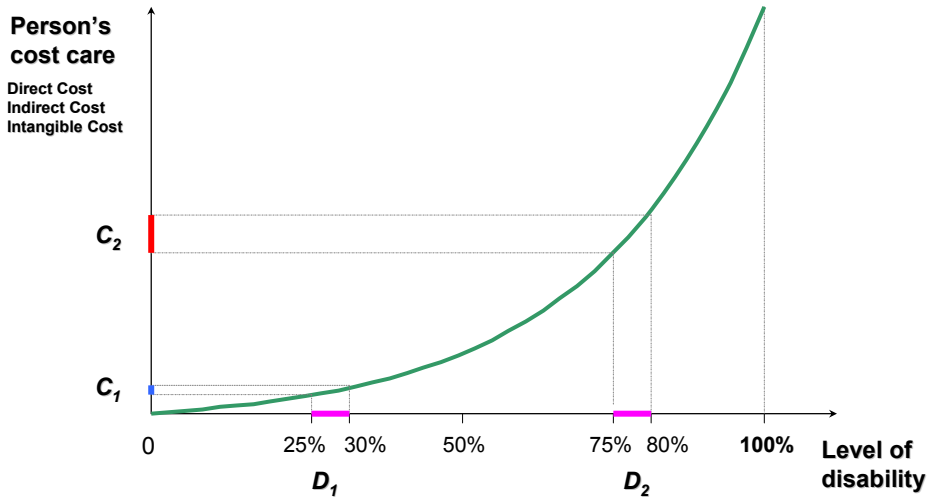

Figure 18. Relationship between levels of disability and the cost for taking care of a disabled person *(Source: our elaboration)*

The proposed example well shows as a 5% increasing variation of level of disability starting from two different degrees of disability, respectively from 25% to 30% - called D_1 - and from 75% to 80% - called D_2, has a different impact on the person's life and therefore on the level of costs that have to be considered for the management of the care of the disabled person.; C_1 measures the increase of care cost corresponding to D_1 and C_2 measures the D_2 increasing: evidently, C_2 is larger than C_1.

Therefore, in the theoretical approach proposed, we underline that Alladin is always very useful, but its importance is higher in severe and very severe stroke than in stroke with a low level of severity; the savings in social costs increase as stroke severity increases.

The monetary evaluation of these savings is deeply country specific and a further analysis would be interesting to be run.

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Appendix

DIAGNOSTIC PHASE

Diagnostic procedures (check the box)

Level of severity for stroke: mild

TRADITIONAL METHOD	ALLADIN
❑ Cerebral angiography	❑ Cerebral angiography
❑ Angio-MRI encephalus	❑ Angio-MRI encephalus
❑ Transcranial doppler	❑ Transcranial doppler
❑ ECG	❑ ECG
❑ Transesophageal echocardiography	❑ Transesophageal echocardiography
❑ Transthoracic echocardiography	❑ Transthoracic echocardiography
❑ Extracranial carotid and vertebral duplex ultrasonography	❑ Extracranial carotid and vertebral duplex ultrasonography
❑ EEG	❑ EEG
❑ Vital signs monitoring	❑ Vital signs monitoring
❑ RMI encephalus	❑ RMI encephalus
❑ Other RMI	❑ Other RMI
❑ X-ray chest	❑ X-ray chest
❑ Other X-ray	❑ Other X-ray
❑ CT encephalus	❑ CT encephalus
❑ Other CT	❑ -Other CT
❑ Haemato-chemical examinations	❑ Haemato-chemical examinations
❑ Neuropsychological tests	❑ Neuropsychological tests
❑ Specialist visit	❑ Specialist visit

DIAGNOSTIC PHASE

Level of severity for stroke: moderate

TRADITIONAL METHOD	ALLADIN
❑ Cerebral angiography ❑ Angio-MRI encephalus ❑ Transcranial doppler ❑ ECG ❑ Transesophageal echocardiography ❑ Transthoracic echocardiography ❑ Extracranial carotid and vertebral duplex ultrasonography ❑ EEG ❑ Vital signs monitoring ❑ RMI encephalus ❑ Other RMI ❑ X-ray chest ❑ Other X-ray ❑ CT encephalus ❑ Other CT ❑ Haemato-chemical examinations ❑ Neuropsychological tests ❑ Specialist visit	❑ Cerebral angiography ❑ Angio-MRI encephalus ❑ Transcranial doppler ❑ ECG ❑ Transesophageal echocardiography ❑ Transthoracic echocardiography ❑ Extracranial carotid and vertebral duplex ultrasonography ❑ EEG ❑ Vital signs monitoring ❑ RMI encephalus ❑ Other RMI ❑ X-ray chest ❑ Other X-ray ❑ CT encephalus ❑ Other CT ❑ Haemato-chemical examinations ❑ Neuropsychological tests ❑ Specialist visit

DIAGNOSTIC PHASE

Level of severity for stroke: severe/very severe

TRADITIONAL METHOD	ALLADIN
❑ Cerebral angiography	❑ Cerebral angiography
❑ Angio-MRI encephalus	❑ Angio-MRI encephalus
❑ Transcranial doppler	❑ Transcranial doppler
❑ ECG	❑ ECG
❑ Transesophageal echocardiography	❑ Transesophageal echocardiography
❑ Transthoracic echocardiography	❑ Transthoracic echocardiography
❑ Extracranial carotid and vertebral duplex ultrasonography	❑ Extracranial carotid and vertebral duplex ultrasonography
❑ EEG	❑ EEG
❑ Vital signs monitoring	❑ Vital signs monitoring
❑ RMI encephalus	❑ RMI encephalus
❑ Other RMI	❑ Other RMI
❑ X-ray chest	❑ X-ray chest
❑ Other X-ray	❑ Other X-ray
❑ CT encephalus	❑ CT encephalus
❑ Other CT	❑ Other CT
❑ Haemato-chemical examinations	❑ Haemato-chemical examinations
❑ Neuropsychological tests	❑ Neuropsychological tests
❑ Specialist visit	❑ Specialist visit

DIAGNOSTIC PHASE

Information related to the healthcare services provided and the professionals involved in this phase

TRADITIONAL METHOD				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

ALLADIN				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

Legend

Professional's skills: the professionals (physician, nurse, physiotherapist…) involved in each service provided
Number of professionals involved: the number of professionals (physician, nurse, physiotherapist…) involved in each service provided
Mean time spent for services provided: the average time that each professional spent for each service provided

ASSESSMENT PHASE
(during rehabilitation treatment)

Information related to the healthcare services provided and the professionals involved in this phase

Level of severity for stroke: mild

TRADITIONAL METHOD				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

ALLADIN				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……..	❑ ……..	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

ASSESSMENT PHASE

Level of severity for stroke: moderate

TRADITIONAL METHOD				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……	❑ ……	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……	❑ ……	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

ALLADIN				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……	❑ ……	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
❑ ……	❑ ……	❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..
		❑ ……..	❑ ……..	❑ ……..

ASSESSMENT PHASE

Level of severity for stroke: severe/very severe

TRADITIONAL METHOD				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……	❑ ……	❑ ……	❑ ……	
		❑ ……	❑ ……	
		❑ ……	❑ ……	
❑ ……	❑ ……	❑ ……	❑ ……	
		❑ ……	❑ ……	
		❑ ……	❑ ……	

ALLADIN				
Type of services provided	Number of services provided per type	Professional's skills requested	Number of professionals involved	Mean time spent for services provided
❑ ……	❑ ……	❑ ……	❑ ……	❑ ……
		❑ ……	❑ ……	❑ ……
		❑ ……	❑ ……	❑ ……
❑ ……	❑ ……	❑ ……	❑ ……	❑ ……
		❑ ……	❑ ……	❑ ……
		❑ ……	❑ ……	❑ ……