AMICA

Autonomy Motivation & Individual Self-Management for COPD patients (AMICA)

DELIVERABLE D2 Analysis of existing COPD healthcare processes

Workpackage WP5 – Healthcare Processes and Disease Management

Version	**3.2**	**Date**	12/10/2009	**Classification**	PUBLIC	**Status**	Released

Abstract

The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the disease management and medical care of chronic obstructive pulmonary disease (COPD) patients. AMICA is a Research and Development project sponsored under the Europeans Commission's Ambient Assisted Living programme as well as its projects members. Its official website is http://www.amica-aal.com.

AMICA project started April 2009 and lasts for 3 years until April 2012 with a total budget of €4M. Seven partners spread across Europe are involved including medical companies and foundations (Vitaphone - Germany, I.S.S- Spain. and the Foundation for Biomedical Research Management- Spain), Academics (Institute of Communication and Computer Systems from the National Technical University of Athens- Greece, the Engineering School from Cádiz– Spain and the Research Centre for Information Technology from Karlsruhe – Germany) and an electronic design company (M.S.C.- Spain/Germany).

Deliverable 2 belongs to Workpackage 5. It includes information about the health system of different countries (United Kingdom, Spain, United States, Greece, Sweden and Norway). These countries have been chosen for two different reasons. On one side, some of them are the countries of the partners of the consortium (Spain, Greece and Germany which will be developed by Vitaphone in the whole report) and on the other side, some have been chosen as representative of the most relevant health systems in the world (USA, UK, Sweden and Norway).

Vitaphone, Innovaciones Sociosanitarias, FZI Forschungszentrum Informatik and ICCS (Institute of Communication and Computer Systems) have contributed to this report.

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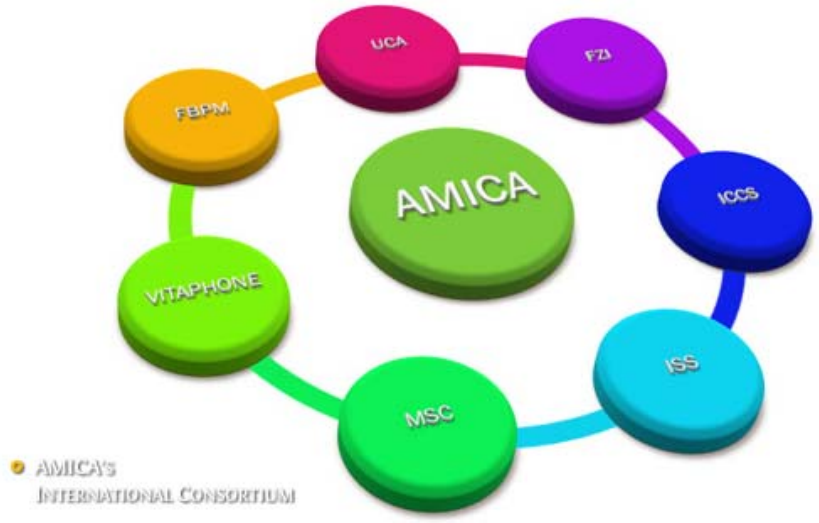
AMICA PARTNERS



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BACKGROUND

The purpose of this section is to introduce the:

- ✓ AMICA Project
- ✓ Purpose, scope and context of this deliverable
- ✓ Intended audience for the deliverable
- ✓ Document Structure
- ✓ External References

AMICA Project

The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the **disease management** and **medical care of chronic obstructive pulmonary disease (COPD) patients**. AMICA is a Research and Development project sponsored under the Europeans Commission's Ambient Assisted Living programme as well as its projects members. Its official website is http://www.amica-aal.com.

It is aimed at providing medical management and medical care to patients suffering from Chronic Obstructive Pulmonary Disease (COPD). COPD is a progressive pulmonary disease characterized by reduction in airflow and is not fully reversible. COPD is the major cause of mortality and increased levels of disability, particularly in the elderly. Symptoms vary among individuals and include breathlessness, dyspnea, abnormal sputum and chronic cough. Exposure to tobacco smoke is by far the most important risk factor in the development of COPD and is associated with high levels of morbidity and mortality.

AMICA'S main objective is to develope and assess long-term COPD management solutions based on innovative Information and Communication Technologies (ICT) that:

- ✓ Allows early detection of COPD exacerbations through the use of a multifunction biomedical system able to yield continuous and sporadic data on heart, breathing and physical activity. This helps to avoid hospitalization and enhances quality of life of elderly COPD patients.
- ✓ Offers a user-friendly design for the elderly.
- ✓ Provides remote monitoring and home-based care
- ✓ Integrates a technical solution with a holistic service approach.
- ✓ Fosters prevention and self-management through immediate comprehensive feedback and efficient personalized assistance.
- ✓ Increases levels of therapy compliance providing effective incentives schemes such as health treatments abroad as an added bonus while it reduces public

health care costs and provides business opportunities on the health tourism market.

AMICA project started April 2009 and lasts for 3 years until April 2012 with a total budget budget of 2.783.139,48€. Seven partners spread across Europe are involved including medical companies and foundations (Vitaphone - Germany, I.S.S- Spain. and the Foundation for Biomedical Research Management- Spain), Academics (Institute of Communication and Computer Systems from the National Technical University of Athens- Greece, the Engineering School from Cádiz– Spain and the Research Centre for Information Technology from Karlsruhe – Germany) and an electronic design company (M.S.C.- Spain/Germany).

Deliverable purpose, scope and context

This report is part of Workpackage 5. It includes information about the health system of different countries chosen as representative of the most relevant health systems in the world.

Audience

This document is considered as a PUBLIC deliverable report. The intended audience includes the partners affected by work package number 6.

Document Structure

This document is structured as follows:

- ✓ **Section 0: Background** - provides background information about the deliverable.
- ✓ **Section 1: General information about the national healthcare system** - includes a description of the most relevant healthcare systems.
- ✓ **Section 2: COPD as a chronic disease of the pulmonary system –** includes the national COPD management approach, health political and health economical aspects and main research projects aboarded in these countries.

References

This document is dependent on the following references:

- ✓ AMICA:
  - o [AMICA D1] AMICA Deliverable D1

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GENERAL INFORMATION ABOUT THE NATIONAL HEALTHCARE SYSTEM.

1.- Structure & specifics.

1.1 United Kingdom.

Since its launch 60 years ago, the National Health System (NHS) has grown to become the world's largest publicly funded health service. It is also one of the most efficient, most egalitarian and most comprehensive.

The system was born out of a long-held ideal that good healthcare should be available to all, regardless of wealth – and that principle remains at its core. With the exception of charges for some prescriptions and optical and dental services, the NHS remains free at the point of use for anyone who is resident in the UK – more than 60m people. It covers everything from antenatal screening and routine treatments for coughs and colds to open heart surgery, accident and emergency treatment and end-of-life care.

Although funded centrally from national taxation, NHS services in England, Northern Ireland, Scotland and Wales are managed separately. While some differences have emerged between these systems in recent years, they remain similar in most respects and continue to be talked about as belonging to a single, unified system.

Basic elements:

The Department of Health (DH) is in overall charge of the NHS with a cabinet minister reporting as secretary of state for health to the prime minister. The department has control of England's 10 Strategic Health Authorities (SHAs), which oversee all NHS activities in England. In turn, each SHA is responsible for the strategic supervision of all the NHS trusts in its area. The devolved administrations of Scotland, Wales, and Northern Ireland run their local NHS services separately.

Measuring the efficiency of healthcare systems is notoriously difficult. The NHS – in common with other healthcare systems – has never consistently and systematically measured changes in its patients' health. As a result, it's impossible to say exactly how much extra "health" is created for each pound spent.

Nevertheless, in the UK life expectancy has been rising and infant mortality has been falling since the NHS was established. Both figures compare favourably with other nations. Surveys also show that patients are generally satisfied with the care they receive from the NHS. Importantly, people who have had recent direct experience of the NHS tend to report being more satisfied than people who have not.(National Health Service, United Kingdom, 2010)

Health insurance system

As can be seen on the diagram below (figure 1) the NHS is divided into two sections: primary and secondary care.

Primary care is generally regarded as a "frontline" service. It is the first point of contact for most people and is delivered by a wide range of independent contractors such as GPs, dentists, pharmacists and optometrists.

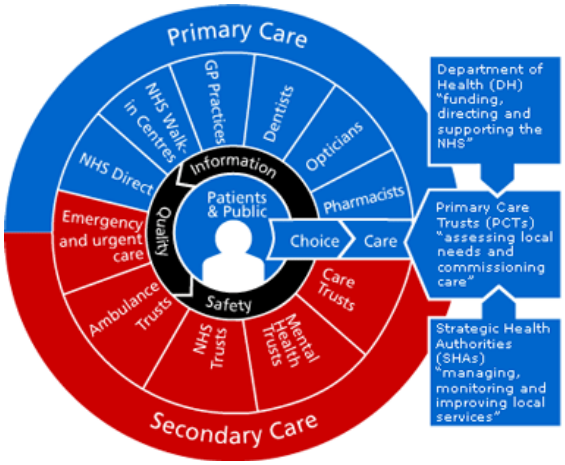

Figure 1. Graphic representation of the British National Health System.

Secondary care is known as acute health care and can be either elective care or emergency care. Elective care means planned specialist medical care or surgery, usually following referral from a primary or community health professional such as a GP.

Primary Care Trusts (PCTs) are in charge of primary care and have a major role around commissioning secondary care, providing community care services. They are now at the centre of the NHS and control 80% of the NHS budget. As they are local organisations, they are best positioned to understand the needs of their community, so they can make sure that the organisations providing health and social care services are working effectively. The PCTs oversee 37,000 GPs and 21,000 NHS dentists.

There are 168 acute NHS trusts and 73 mental health NHS trusts which oversee 1,600 NHS hospitals and specialist care centres. Foundation trusts are a new type of NHS hospital of which there are currently 122 available across England.

Emergency vehicles are provided by the NHS ambulance services trusts. There are 12 ambulance trusts in England. The Scottish, Welsh and Northern Ireland ambulance services provide cover for those countries.

NHS care trusts provide care in both health and social fields. There are few care trusts and they are based mainly in England. There are none in Scotland and the Scottish NHS has no plans to introduce them.

NHS mental health services trusts provide mental health care in England and are overseen by the PCT.

There are also agencies under the umbrella of the NHS. These include the National Institute for Health and Clinical Excellence (NICE).(National Health Service, United Kingdom, 2010)

The NHS was born out of a long-held ideal that good healthcare should be available to all, regardless of wealth. At its launch by the then minister of health, Aneurin Bevan, on July 5 1948, it had at its heart three core principles:

- that it meet the needs of everyone,

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- that it be free at the point of delivery, and
- that it be based on clinical need, not ability to pay.

These three principles have guided the development of the NHS over more than half a century and remain. However, in July 2000, a full-scale modernisation programme was launched and new principles added. These require that:

The NHS will provide a comprehensive range of services. The NHS will provide access to a comprehensive range of services throughout primary and community healthcare, intermediate care and hospital-based care. The NHS will also provide information services and support to individuals in relation to health promotion, disease prevention, self-care, rehabilitation and after-care.

The NHS will shape its services around the needs and preferences of individual patients, their families and their carers. The NHS must be responsive to the needs of different groups and individuals within society. The NHS will treat patients as individuals, with respect for their dignity.

The NHS will respond to the different needs of different populations Health services will continue to be funded nationally and be available to all citizens of the UK.

The NHS will work continuously to improve the quality of services and to minimise errors. Healthcare organisations and professions will establish ways to identify procedures that should be modified or abandoned and new practices that will lead to improved patient care. All those providing care will work to make it ever safer and support a culture where we can learn from and effectively reduce mistakes.

The NHS will support and value its staff. The NHS will continue to support, recognise, reward and invest in individuals and organisations, providing opportunities for individual staff to progress in their careers and encouraging education, training and personal development.

Public funds for healthcare will be devoted solely to NHS patients The NHS is funded out of public expenditure, primarily by taxation. This is a fair and efficient means of raising funds for healthcare services.

The NHS will work with others to ensure a seamless service for patients The health and social care system must be shaped around the needs of patients. The NHS will develop partnerships and co-operation at all levels of care:

- between patients, their carers, families and NHS staff,
- between the health and social care sectors,
- between different government departments, and
- between the public sector, voluntary organisations and private providers in the provision of NHS services.

The NHS will help to keep people healthy and work to reduce health inequalities The NHS will focus efforts on preventing, as well as treating, ill health. Recognising that good health also depends upon social, environmental and economic factors such as deprivation, housing, education and nutrition, the NHS will work with other public services to intervene not just after but before ill-health occurs.

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The NHS will respect the confidentiality of individual patients and provide open access to information about services, treatment and performance Patient confidentiality will be respected throughout the process of care. The NHS will be open with information about health and healthcare services. It will continue to use information to improve the quality of services for all and to generate new knowledge about future medical benefits. Developments in science, such as the new genetics, offer important possibilities for disease prevention and treatment in the future. As a national service, the NHS is well-placed to take advantage of the opportunities offered by scientific developments and will ensure that new technologies are harnessed and developed in the interests of society as a whole and available to all on the basis of need.(National Health Service, United Kingdom, 2010)

The Care Quality Commission (CQC) The CQC regulates all health and adult social care services in England, whether they're provided by the NHS, local authorities, private companies or voluntary organisations. And, it protects the interests of people detained under the Mental Health Act.

It makes sure that essential common quality standards are being met where care is provided, from hospitals to private care homes, and works towards their improvement. It promotes the rights and interests of people who use services and has a wide range of enforcement powers to take action on their behalf if services are unacceptably poor.

CQC's work brings together independent regulation of health, mental health and adult social care for the first time. Before April 1 2009, this work was carried out by the Healthcare Commission, the Mental Health Act Commission and the Commission for Social Care Inspection.

CQC's aim is to make sure better care is provided for everyone, whether that's in hospital, in care homes, in people's own homes, or elsewhere.

Throughout CQC's work it makes sure that the voices of people who use health and adult social care services are heard. It asks people to share their experiences of care services and to give them their views. It makes sure they are at the heart of its reports and reviews. In some cases CQC involves patients and their carers directly in working alongside their inspectors to give an expert user view of services.

By law all NHS providers such as hospitals and ambulance services must register with CQC from April 1 2009, to show they are protecting people from the risk of infection. The registration system applies to NHS provider trusts (acute, ambulance, mental health and primary care) and the NHS Blood and Transplant Authority.

From April 2010 all regulated health and adult social care providers must be registered with CQC to show they are meeting a wide range of essential, common quality standards. Without registration, providers will not be allowed to operate.

Enforcement. If providers don't meet essential quality standards, or if CQC has reason to think that people's basic rights or safety are at risk, it takes action.

CQC has a new, wide range of enforcement powers, such as fines and public warnings, and has flexibility about how and when to use them. It can apply specific conditions in response to serious risks. For example, it can demand that a hospital ward or service is closed until the

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provider meets safety requirements or is suspended. Or, it can take a service off the register if absolutely necessary.

In its first year its new powers will apply to NHS providers only in relation to healthcare-associated infections, but the full range of powers will apply to all health and adult social care providers as full registration is phased in from April 2010.

Improvement. As well as making sure essential quality standards are in place through the registration system, CQC helps to drive up improvements across health and social care through periodic and special reviews and assessments of commissioning.

CQC's priority is to improve the public's experience of health and social care and to improve outcomes - what happens to people as a result of the care they receive.(National Health Service, United Kingdom, 2010)

Financial streams

Nationwide, the NHS employs more than 1.7m people. Of those, just short half are clinically qualified, including some 120,000 hospital doctors, 40,000 general practitioners (GPs), 400,000 nurses and 25,000 ambulance staff.

Only the Chinese People's Liberation Army, the Wal-Mart supermarket chain and the Indian Railways directly employ more people.

The NHS in England is far and away the biggest part of the system, catering to a population of 51m and employing more than 1.3m people. The NHS in Scotland, Wales and Northern Ireland employ 165,000, 90,000 and 67,000 people respectively.

The number of patients using the NHS is equally mind-boggling. On average, it deals with 1m patients every 36 hours - that's 463 people a minute or almost 8 a second. Each week, 700,000 will visit an NHS dentist, while a further 3,000 will have a heart operation. Each GP in the nation's 10,000-plus practices sees an average of 140 patients a week.

When the NHS was launched in 1948 it had a budget of £437 million (roughly £9 billion at today's value). In 2008/9 it received 10 times that amount - more than £100 billion.

This equates to an average rise in spending over the full 60-year period of about 4% a year once inflation has been taken into account. However, in recent years investment levels have been double that to fund a major modernisation programme.

Some 60% of the NHS budget is used to pay staff. A further 20% pays for drugs and other supplies, with the remaining 20% split between buildings, equipment and training costs on the one hand and medical equipment, catering and cleaning on the other. Nearly 80% of the total budget is distributed by local trusts in line with the particular health priorities in their areas.

The money to pay for the NHS comes directly from taxation that, according to independent bodies such as the King's Fund, remains the "cheapest and fairest" way of funding health care when compared with other systems. The 2008/9 budget roughly equates to a contribution of £1,980 for every man, woman and child in the UK.(National Health Service, United Kingdom, 2010)

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1.2 Spain

The Spanish health system covers the right for all citizens to enjoy health protection and care is laid down in article 43 of the Spanish Constitution of 1978. The main principles governing the exercise of this right are regulated by the General Health Act 14/1986, as follows:

- Public funding, with universal, free health services at the time of use
- Specific rights and duties for citizens and for public authorities
- Devolution of health affairs to the Autonomous Communities
- Provision of holistic health care, aiming to achieve high quality, with proper evaluation and control
- Inclusion of the different public health structures and services in the National Health System

Basic Elements

The **National Health System** is therefore made up of both the State and Autonomous Community Health Departments and covers all the health functions and services for which the public authorities are legally responsible.

The State powers are:

- General organisation and coordination of health matters
- International health, and international health relations and agreements.
- Legislation on pharmaceutical products.

General organisation and coordination refers to the regulation of conditions and minimum requirements, aiming to achieve equal conditions in the functioning of public health services; the creation of methods for the sharing of information, technical standardisation in specific areas, and joint action by State and Autonomous Community authorities in the exercise of their respective powers.

International health refers to the surveillance and control of possible health risks in connection with the import, export or traffic of goods and international passenger traffic. Spain collaborates with other countries and international organisations through international relations and health agreements:

- In epidemiological control
- In the fight against communicable diseases
- In the protection of a healthy environment
- In the drafting, improvement and implementation of international standards
- In biomedical research and in any actions agreed on which are considered by the parties to be beneficial for health

Regarding *Pharmaceutical products*, the powers held by the State are as follows:

- Legislation on pharmaceutical products
- Evaluation, authorisation and registration of drugs for human and veterinarian use and health products

- Authorisation for public financing and pricing of drugs and health products
- Guaranteeing the deposit of narcotics in accordance with international treaties
- Imports of urgent, foreign medication not authorised in Spain
- Maintenance of a strategic, State-run deposit of drugs and health products for emergencies and catastrophes
- Purchase and distribution of drugs and health products for international cooperation programmes

Irrespective of the powers held by the Autonomous Communities and, where appropriate, in coordination with them, the State Administration also carries out actions in the following areas:

- Health and hygiene control of the environment, foods, services or products that are directly or indirectly related to human use and consumption
- Regulation, authorisation and registration or standardisation of drugs for human and veterinary use and, for the former, inspection and quality control
- Promotion of rational drug use
- General determination of the conditions and minimum technical requirements for the approval and standardisation of facilities and equipment in centres and services
- Promotion of quality in the National Health System
- Specialised training in accredited teaching centres and units
- Creation of the NHS Information System

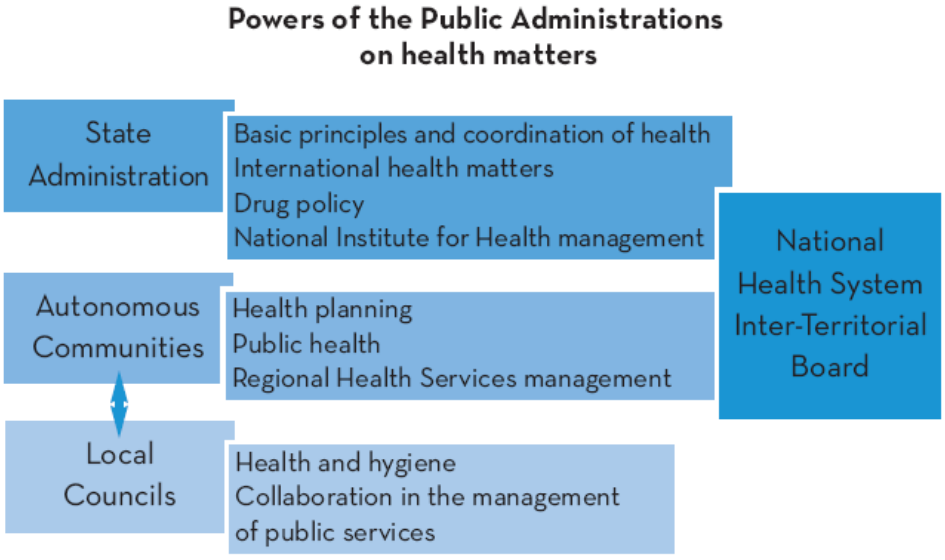

Figure 2. Representation of the Spanish Public Administrations on health matters.

Each Autonomous Community has a **Regional Health Service**, which is the administrative and management body responsible for all the centres, services, and facilities in its own Community,

whether these are organised by regional or town councils or other intra-Community Administrations (figure 2).

The principles governing health coordination on a nationwide level are laid down in the General Health Act 14/1986 of 25 April, which also specifies the tools for collaboration and creates the National Health System's **Inter- Territorial Board** as the coordinating body. Subsequently, **Act 16/2003 of 28 May on Cohesion and Quality in the National Health System** deals in greater depth with the role of the Inter-Territorial Board as the coordinating body and with general coordination and cooperation within the National Health System.

The devolution of powers to the Autonomous Communities is a means of bringing the management of health care closer to citizens and thus guaranteeing equity, quality and participation. Practical experience of relations between the State and the Autonomous Communities in the area of health protection provides important references for the development of cohesion in the State of Autonomous Communities. All those involved are working to achieve a common identity for the National Health System, based on the constitutional principles of unity, autonomy and solidarity.

The Law on Cohesion and Quality in the National Health System therefore requires coordination and cooperation amongst the public health administrations in order to guarantee the right to health protection and to ensure:

a) Equity, according to the constitutional principle of equality, guaranteeing access to services and the right to health protection in conditions of real equality throughout the Spanish territory and allowing free movement by all citizens.

b) Quality, with the inclusion of safe and effective innovations, and orienting the system towards the anticipation and effective solution of health problems. The benefit of clinical actions should be evaluated, so that only those actions that improve health are taken, involving all agents in the system.

c) Participation by citizens, regarding both autonomy in their individual decisions and the consideration of their expectations as users of the health system, in order to facilitate the exchange of knowledge and experience.

The rights to health protection and health care are held by:

- All Spanish nationals and aliens within the Spanish national territory in the terms of article 1.2 of Organic Law 4/2000.
- The nationals of European Union Member States who hold entitlement according to Community law and any applicable treaties and conventions signed by the Spanish State
- The nationals of non-European Union Member States whose rights are recognised by any applicable laws, treaties and conventions.

Spanish civil servants and their dependants may have recourse to special insurance regimes through the civil, military or judiciary mutual funds (MUFACE, ISFAS and MUGEJU respectively).

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Health insurance system

The Spanish National Health System is organised in line with its basic principles. Since it aims to provide universal support, it has to ensure equal access to services for all citizens and, since it is financed with public funds, expenditure must be based on efficiency criteria.

The System is therefore organised at two care levels in which accessibility and technological complexity are counterpoised.

The first level – **Primary Health Care** – is characterised by extensive accessibility and sufficient technical resources to resolve the most frequent health problems.

The second level – **Specialist Care** – has more complex and costly diagnostic and therapeutic resources which have to be concentrated in order to be efficient. Access is gained by referral from Primary Health Care.

Primary Health Care aims to provide basic services within a 15-minute radius from any place of residence. The main facilities are the *Primary Care Centres* which are staffed by multi-disciplinary teams comprising general practitioners, paediatricians, nurses and administrative staff and, in some cases, social workers, midwives and physiotherapists. Since this level is located within the community, it also deals with health promotion and preventive health care. Maximum accessibility and equity means that Primary Health Care also reaches homes when necessary.

Specialist Care is given in *Specialist Centres and Hospitals*, for both in- and out-patients. Once care is complete, the patient is referred back to the Primary Health Care doctor who uses the full medical history as a basis for subsequent treatment and overall care. This means that continued care is given in equitable conditions, irrespective of the place of residence and individual circumstances, and care will be given in the patient's home if necessary.

Each Autonomous Community establishes its own **Health Areas** according to demographic and geographic criteria aiming, above all, to guarantee service proximity for users. The Health Areas are then sub-divided into Basic Health Zones, which are the territorial framework for Primary Health Care and the Primary Care Centres. Each Area has a general hospital for Specialist Care. In some Health Departments there are intermediate structures between the Health Area and the Basic Health Zone.

The services offered by the Spanish National Health System include preventive care, diagnostic and therapeutic techniques, rehabilitation and health promotion and maintenance.

Primary Care

This is the level involving most of the activities in the field of health promotion, health education and preventive medicine. Health care is delivered both on demand and in a programmed way and in Primary Care Centres, rural outpatients' centres and patients' homes. Medical and nursing care is also provided round-the clock – in patients' homes, if necessary – for urgent health problems. Finally, physical rehabilitation and social support services are also offered.

Specific activities are also carried out, most of them focusing on specific groups:

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- *Women:* Family counselling, monitoring of pregnancy, birth preparation, post-natal care, scanning for cervical and breast cancer, treatment of pathological complications of the menopause
- *Children:* Healthy child check-ups, vaccinations and health education for parents, tutors, teachers and carers
- *Adults and the elderly:* Vaccinations, detection of risk factors, education, care for chronic patients, specific problems of the elderly and home care for the disabled and terminal patients
- *Oral and dental health:* Information and education for children, preventive measures and treatment of acute processes, preventive examinations in pregnant women
- *Terminal patients:* Palliative care and home visits
- *Mental health:* Detection and care for mental health problems in coordination with the specialist level

Specialist Care

This includes care, diagnostic and therapeutic activities and rehabilitation. Care activities include those aspects of health promotion, education and prevention which are best carried out at this level.

Services are provided for both out- and in-patients, sometimes via day hospitals which mainly offer out-patient surgery and diagnostic and therapeutic techniques requiring special monitoring.

Out-patient consultations are offered by the different medical and surgical specialists and diagnostic and therapeutic activities are carried out. In Mental Health and Psychiatric Care, diagnosis and clinical monitoring are carried out, with drug therapy and individual, group or family psychotherapy and hospitalisation as required, with the express exclusion of psychoanalysis and hypnosis.

Hospitalised patients receive medical, surgical, obstetric and paediatric care for severe diseases and recurring chronic processes, with treatments or diagnostic procedures as required.

Emergency care is available 24 hours a day for out-patients.

Other services

- Haemotherapy
- Fertility diagnosis and treatment
- Prenatal diagnosis in at-risk groups
- Diagnosis through imaging
- Laboratories
- Renal lithotripsy
- Family planning
- Interventional radiology
- Radiotherapy
- Transplants

Pharmaceutical services

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These cover drugs and health products as well as actions aiming to ensure that patients receive drugs as required, at the correct dosage, during the right amount of time and at the lowest possible cost for them and for the community.

Unlike other services which are provided free of charge, pharmaceutical, orthopaedic and prosthetic services are co-financed by users (table 1)

	Population with Social Security protection	Population with Public Mutual Fund protection
Pensioners and their beneficiaries	0%	30%
Non-pensioners and their beneficiaries	40%	30%
Specific groups		
Toxic Syndrome patients	0%	
AIDS patients	10% (2.69 € maximum)	
Chronic patients	10% (2.69 € maximum)	

Source: Ministry of Health and Consumer Affairs. Directorate General for Pharmacy and Health Products

Table 1. Percentages of cofinancing of the Pharmaceutical services by users.

Hospital pharmacy: Drugs dispensed during hospitalisation or specialist care are fully publicly financed.

Medical prescriptions: When drugs covered by the Social Security or State funds for health care within the National Health System are prescribed and dispensed to non-hospitalised patients, co-financing works as shown in the chart.

Orthopaedic and prosthetic services

These cover the elements required to improve patients' quality of life and degree of autonomy. They include health products, whether implants or not, that totally or partially replace a body structure or modify, correct or facilitate its function.

Services are laid down in a specific catalogue.

Health transport

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This service is the transport of patients for clinical purposes when their situation does not allow them to use ordinary means of transport, in emergencies or when the patient is physically incapacitated.

Dietary products

This service refers to the dispensing of dietary treatments to people with certain congenital metabolic disorders, and enteral feeding in patients' homes when their clinical situation does not allow them to ingest ordinary food.

Information and Health Documentation Services

The National Health System also offers a number of services that complement health care:

- Information for patients and their families on their rights and obligations, especially regarding informed consent.
- Administrative procedures to guarantee continued care.
- Issue of medical certificates for employers and other reports or clinical documents for assessing incapacity, etc.
- Hospital discharge report and out-patients' reports.
- Certification of births, deaths, etc. for the Civil Register Office.
- At the request of users, the provision of their clinical records or specific data contained in them, while observing the obligation of preserving such records in the Health Centre.
- The issue of reports or certificates on the condition of health as required for other health services or for legal or regulatory reasons.

Financial streams

The Spanish population official figures, as registered on January 1st 2008 census, totals: 46,157,822 inhabitants, of which, 5,268,762 (11.4% of the total) are not Spanish citizens.

The pyramid reveals a demographic structure characteristic of a significant ageing of the population, with 16.5% aged 65 or older.

Access to services is gained on presentation of the Personal Health Card issued by the respective Health Department. This document identifies each citizen as a user for the whole National Health System.

The National Health System has 2,914 Primary Care Centres. There are also medical centres in small towns to which the staff of the zone's Primary Care Centre travels in order to provide basic services to the local population. These are mostly in rural areas, which tend to have a high proportion of elderly patients.

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HEALTH CENTRES IN SPAIN, 2008			
	Control	Centres	Beds
Primary Care Centres	Public	2,914	...
Hospitals	Public Civil Hospital	315	105,505
	Ministry of Defence	4	995
	Occupational accident and work-related illnesses Mutual Societies	20	1,468
	Private	465	53,013
	TOTAL	**804**	**160,981**

Source: Ministry of Health and Social Policy, Health Information Institute.

Table 2: Number of Health Centres in Spain, 2008

There are 804 hospitals operating in Spain. The National Health System has 315 hospitals, equipped with 105,505 beds, and 4 Ministry of Defence's hospitals contributing with 995 beds. There are also 20 hospital facilities owned by the occupational accident and work-related illnesses mutual societies, with 1,468 beds.

The remainder, 465 hospitals, are privately run and have 53,013 beds (table 2).

According to the kind of care provided, from the total of 160,981 beds installed in Spain's hospitals, 131,445 are located in 589 hospitals concerned with acute care, 72.9% of which are managed by the National Health System. 37.2% of the 16,111 beds available in psychiatric care hospitals and 35.1% of the 13,365 beds for geriatric and long-term care are managed by the National Health System (table 3).

NUMBER OF BEDS, 2008			
	Beds	Rate per 100,000 inhabitants	% Public
Acute Care	131,445	284.7	72.9%
Psychiatric Care	16,111	34.9	37.2%
Geriatric Care	13,365	28.9	35.1%
Total	**160,981**		

Source: Ministry of Health and Social Policy, Health Information Institute.

Table 3: Number of beds in Spanish Health System, 2008

Health care in Spain is **a non-contributory benefit**. It is paid for through taxation and is included in the general budget for each Autonomous Community. Two additional funds are the Cohesion Fund managed by the Ministry of Health and Consumer Affairs and the Savings Programme for Temporary Incapacity.

Health care is one of the main instruments of policies to redistribute income amongst Spanish citizens: all citizens pay taxes in line with their financial capacity and receive health services as needed.(Ministerio de Sanidad y Política Social, Instituto de Información Sanitaria, 2010)

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1.3 United States of America.

The U.S. health care system is the subject of much polarizing debate. At one extreme are those who argue that Americans have the "best health care system in the world", pointing to the freely available medical technology and state-of-the-art facilities that have become so highly symbolic of the system. At the other extreme are those who berate the American system as being fragmented and inefficient, pointing to the fact that America spends more on health care than any other country in the world yet still suffers from massive uninsurance, uneven quality, and administrative waste.

Understanding the debate between these two diametrically opposed viewpoints requires a basic understanding of the structure of the U.S. health care system. This primer will explain the organization and financing of the system, as well as place the U.S. health care system in a greater international context.

Health insurance system

As with all other countries, there are both private and public insurers in the U.S. health care system. What is unique about the U.S. system in the world is the dominance of the private element over the public element.

In 2003, 62% of non-elderly Americans received private employer-sponsored insurance, and 5% purchased insurance on the private non group (individual) market. 15% were enrolled in public insurance programs like Medicaid, and 18% were uninsured. Elderly individuals aged 65 or over are almost uniformly enrolled in Medicare.

Public Health Insurance

• Medicare

Basics: Medicare is a federal program that covers individuals aged 65 and over, as well as some disabled individuals.

Administration: Medicare is a single-payer program administered by the government; single-payer refers to the idea that there is only one entity (the government) performing the insurance function of reimbursement.

Financing: Medicare is financed by federal income taxes, a payroll tax shared by employers and employees, and individual enrollee premiums (for parts B and D).

Benefits: Medicare Part A covers hospital services, Medicare Part B covers physician services, and Medicare Part D offers a prescription drug benefit. [Medicare Part C refers to Medicare Advantage – HMO's that administer Medicare benefits].

There are many gaps in Medicare coverage, including incomplete coverage for skilled nursing facilities, incomplete preventive care coverage, and no coverage for dental, hearing, or vision care. Because of this, the vast majority of enrollees obtain supplemental insurance. Overall, seniors pay about 22% of their income for health care costs despite their Medicare coverage.

• Medicaid

Basics: Medicaid is a program designed for the low-income and disabled. By federal law, states must cover very poor pregnant women, children, elderly, disabled, and parents. Childless adults are not covered, and many poor individuals make too much to qualify for Medicaid.

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States have the option of expanding eligibility if they so choose. For example, states can choose to increase income eligibility levels.

Administration: The states and the District of Columbia are responsible for administering the Medicaid program; as such, there are effectively fifty-one different Medicaid programs in the country.

Financing: Medicaid is financed jointly by the states and federal government through taxes. Every dollar that a state spends on Medicaid is matched by the federal government at least 100%. In poorer states, the federal government matches each dollar more than 100%. Overall, the federal government pays for 57% of Medicaid costs.

Benefits: Medicaid offers a fairly comprehensive set of benefits, including prescription drugs. Despite this, many enrollees have difficulty finding providers that accept Medicaid due to its low reimbursement rate.

• Other public systems

S-CHIP: The State Children's Health Insurance Program (S-CHIP) was designed in 1997 to cover children whose families make too much money to qualify for Medicaid but make too little to purchase private health insurance. S-CHIP and Medicaid often share similar administrative and financing structures.

VA: The Veteran's Administration is a federally administered program for veterans of the military. Health care is delivered in government-owned VA hospitals and clinics. The VA is funded by taxpayer dollars and generally offers extremely affordable (if not free) care to veterans.

Private Health Insurance

• Employer-sponsored insurance

Basics: Employer-sponsored insurance represents the main way in which Americans receive health insurance. Employers provide health insurance as part of the benefits package for employees.

Administration: Insurance plans are administered by private companies, both for-profit (e.g. Aetna, Cigna) and non-for-profit (e.g. Blue Cross/Blue Shield).

A special case is represented by companies that are "self-insured" – that is, they pay for all health care costs incurred by employees directly. In this case, the company contracts with a third party to administer the health insurance plan. Self-insured companies tend to be larger companies such as General Motors.

Financing: Employer-sponsored insurance is financed both through employers (who usually pay the majority of the premium) and employees (who pay the remainder of the premium). In 2005, the annual private employer-sponsored insurance premiums averaged $4,024 for single coverage and $10,880 for a family of four.5

Benefits: Benefits vary widely with the specific health insurance plan. Some plans cover prescription drugs, while others do not. The degree of cost-sharing (co-pays and deductibles) varies considerably.

• Private non-group (individual market)

Basics: The individual market covers part of the population that is self-employed or retired. In addition, it covers some people who are unable to obtain insurance through their employer. In contrast to the group market (employment-based insurance), the individual market allows health insurance companies to deny people coverage based on pre-existing conditions.

Administration: The plans are administered by private insurance companies.

Financing: Individuals pay an insurance premium out-of-pocket for coverage. Risk in the individual market depends only on the health status of the individual, in contrast to the group market, in which risk is spread out among multiple individuals. As such, low-risk, healthy patients will have a low premium, whereas the opposite is true for high-risk, sick patients.

Benefits: Benefits vary widely with the specific health insurance plan.

Financial streams

The financing of health care centers around two streams of money: the collection of money for health care (money going in), and the reimbursement of health service providers for health care (money going out). In the United States, the responsibility for these two functions is shared by private insurance companies as well as the government, both of which are known in policy terms as "payers." As such, the United States can be thought of as a "multi-payer" system.

• Individuals and businesses

Taxes: Both individuals and businesses pay income taxes to the government. In addition, there is a payroll tax on employers and employees to finance Medicare.

Premiums: Businesses pay all or most of the premium for employer-based insurance for employees, and employees pay the remainder. On the individual market, individuals pay for all premiums out of pocket. Employer-based insurance premiums and individual insurance premiums are collected by private insurers.

Direct or out-of-pocket payments: This is a direct payment to a provider for health care services (e.g. a co-payment).

• Government

Medicare, Medicaid, S-CHIP, and the VA: The government uses money generated from taxes to reimburse providers who take care of patients enrolled in these programs.

Public employees' premiums: The government also uses tax dollars to pay private insurers a health insurance premium for federal employees and other public employees.

Tax subsidy: There is a tax subsidy of employer-based insurance (not shown in the graph) that represents a major cost to the government (on the order of $100 billion). Employees receive health insurance benefits as tax-free compensation, and employers are able to deduct health insurance benefits as a cost of doing business. [Since employers are only taxed on profits, defined as any income above the cost of doing business, being able to deduct health insurance benefits as a cost of doing business is a tax subsidy for employers].

• Private insurers

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Private insurers accept premiums from individuals, businesses, and the government. In turn, they reimburse providers for taking care of patients with private insurance.

• Health service providers

Providers (doctors, allied health professionals, hospitals, and other health care facilities) take care of individuals. They are reimbursed for their services by private insurers and the government.

In 2002, government expenditures accounted for 44.9% of healthcare costs in the United States, and private expenditures accounted for the remaining 55.1%.6 The U.S. spent $1.7 trillion on health care expenditures in 2003. Of the $1.7 trillion used on health care, the majority went to hospital care and physician/clinical services.

The United States spent 15% of its GDP on health care in 2003, the highest percentage in the OECD (an organization of industrialized countries). The average percentage of GDP spent on health care in OECD countries was 8.6%. The United States also spends more on health care per capita than any other OECD country. In 2003, total health spending per capita was $5,635 US dollars (adjusted for purchasing power parity), more than twice the OECD average of $2,307 US dollars.

Between 1998 and 2003, health spending per capita in the United States increased in real terms by 4.6% per year on average, a growth rate comparable to the OECD average of 4.5% per year.

The public sector is the main source of health funding in all OECD countries, except for the United States, Mexico and Korea. In the United States, 44% of health spending is funded by government revenues, well below the average of 72% in OECD countries.

In the United States, private insurance accounts for 37% of total health spending, by far the largest share among OECD countries. Canada, France, and the Netherlands also have a relatively large share of funding coming from private insurance (more than 10%).

RESOURCES IN THE HEALTH SECTOR (HUMAN, PHYSICAL)

• In 2002, the United States had 2.3 practicing physicians per 1000 population, below the OECD average of 2.9 per 1000 population.

• There were 7.9 nurses per 1000 population in the United States in 2002, below the OECD average of 8.2 per 1000 population.

• The number of acute care hospital beds in the United States in 2003 was 2.8 per 1000 population, below the OECD average of 4.1 beds per 1000 population.(Kao-Ping Chua, 2006)

THE CURRENT REFORM

The Administration believes that comprehensive health reform should:

- Reduce long-term growth of health care costs for businesses and government
- Protect families from bankruptcy or debt because of health care costs
- Guarantee choice of doctors and health plans
- Invest in prevention and wellness
- Improve patient safety and quality of care
- Assure affordable, quality health coverage for all Americans

- Maintain coverage when you change or lose your job
- End barriers to coverage for people with pre-existing medical conditions

Progress

- The President signed the Children's Health Insurance Reauthorization Act on February 4, 2009, which provides quality health care to 11 million kids – 4 million who were previously uninsured.
- The President's American Recovery and Reinvestment Act protects health coverage for 7 million Americans who lose their jobs through a 65 percent COBRA subsidy to make coverage affordable.
- The Recovery Act also invests $19 billion in computerized medical records that will help to reduce costs and improve quality while ensuring patients' privacy.The Recovery Act also provides:

  $1 billion for prevention and wellness to improve America's health and help to reduce health care costs;

  $1.1 billion for research to give doctors tools to make the best treatment decisions for their patients by providing objective information on the relative benefits of treatments; and

  $500 million for health workforce to help train the next generation of doctors and nurses.(The White House, 2010)

1.4 Greece.

Basic Elements

The Ministry of Health and Social Solidarity is the leading institution in developing and financing health policies. The Ministry is responsible for provision and financing of the National Health Service as well as health and social services for the poor, the elderly and the disabled; a very small part of health and social services is provided by municipal authorities. Local authorities (52 districts or prefectures), through the Ministry of Health, play a limited role in the administration of 128 NHS hospitals and 176 rural health centers. The Central Health Council (KESY) and Committees for AIDS, Drugs, Cancer, etc., play an advisory role to the Minister.

The insurance funds (IKA, OGA, TEVE, and others) have been under the jurisdiction of the Ministry of Labor and Social Insurance since September 1995. They play a significant role in the provision and financing of ambulatory services. IKA, the largest social insurance fund (50% of the population) covering mainly blue- and white-collar workers, is responsible for the financing and provision of health care services through its wide and decentralized network of primary health care facilities (over 200 urban polyclinics and clinics). OGA, the second largest social insurance fund, covers farmers and their families (25% of the population) who use the NHS services (i.e. rural health centers). The rest of the funds provide health care services to their beneficiaries mainly through contracts with private physicians for the ambulatory sector, and public or private hospitals for secondary and tertiary health care services. Secondary and tertiary care is provided by NHS hospitals which are publicly owned and financed mainly by the state budget as well as by the insurance funds. Apart from the Ministry of Health and the social insurance funds, the private sector plays a significant role in health care provision.

The Ministry of Health and Social Solidarity, through its central and regional services, has the responsibility of planning and implementing health-related activities for public health, medical care and social welfare (social security was separated from the Ministry of Health and Social Solidarity in September 1995). The Ministry also coordinates health-related program activities of private institutions and individuals. The central administration consists of the Minister and four Secretaries (one for health, one for welfare, one general and one responsible for organization and support) on the political side. On the managerial side, there are five general directorates: one for public health, one for medical care, one for administration of the Ministry, one for welfare and one responsible for supports and infrastructures.

There are a few services subordinated directly to the Minister (legal coordination sector, press office and public relations, secretariat of the Central Health Council, strategic planning and policy analysis unit, and offices for problems due to drug use, and related to equity of the sexes) as well as services functioning under special provisions (office of audit board, statistical service, etc.). The Central Health Council (KESY) was established following the 1983 reform. KESY functions as adviser to the Minister on health policy matters especially in the field of the structure and the function of the NHS. The Chairman of KESY is elected only by the medical members of the Council. Several councils and committees work under KESY. Until now, KESY has not managed to produce innovative policies and programs for the NHS or to establish new regional bodies foreseen by the 1983 legislation. Mainly due to its medically-oriented composition, KESY has focused particularly on the medical field, at the expense of the other professions and interests of the health care system. In September 1995, the Ministry of Labor and Social Insurance took over the supervision of the operation and financing of social insurance funds and the services they provide. The Ministry of Defense is responsible for the financing and management of 13 military hospitals which have remained outside the NHS, while the responsibility for the health of prisoners rests with the Ministry of Justice. Theoretically, the Ministry of Health and Social Solidarity is charged with the responsibility for developing health policy in all the areas. In reality, some overlaps between Ministries result in excessively bureaucratic procedures and delays in decision-making, due to unclear lines of responsibilities among ministers and officials.

Health Insurance System

According to the 1983 health care reform legislation, primary health care (PHC) was to be provided by health centers and their provincial clinics in both rural and urban areas. This law, which for the most part is still valid today, laid the foundations for the first time for an NHS. In the area of PHC it anticipated the establishment of a sufficient number of health centers and provincial clinics, as decentralized units covering the health needs of all the citizens in the entire country. Nearly all the health centers envisaged by the legislation for rural areas were constructed and began to offer primary health care services during the 1980s. However, in the case of urban areas, the provisions of the law did not materialize, and the pre-reform situation remained unchanged. This essentially meant the continued operation of a variety of provider settings, both public and private, with significant inequalities in the range of services provided and in their quality.

The various primary health care provider settings can be classified as follows:

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PHC provided through the NHS: This includes health centers (in rural areas), provincial clinics, and public hospital out-patient departments. These services are financed mainly through the state budget and to a smaller extent by insurance funds.

PHC provided through social insurance funds: This includes polyclinics owned and operated by specific insurance funds (mainly IKA). These services are financed by the social insurance funds.

PHC offered through local authority services: This category includes few clinics and welfare services. These services are financed by the state budget through the Ministry of Interior.

PHC provided by the private sector: This includes physicians in private practice who are contracted with one or more insurance funds (financed by the respective insurance fund), physicians in private practice who are not contracted with any insurance fund (financed by out-of-pocket patient payments or voluntary health insurance), and private hospital out-patient departments (financed mainly by out-of-pocket payments or voluntary health insurance).

PHC provided through the NHS

One-hundred-and-seventy-six health centers have been established in rural areas alone, with the intention of providing preventive, curative, and rehabilitation services to their catchment areas (14 000–15 000 population on average). Although they were intended to act as gatekeepers to the health care system, in fact this has not occurred. The health centers are staffed by doctors (who are mainly pathologists, pediatricians and a few general practitioners) and nurses, all of whom are full-time salaried employees of the state. On average there are seven beds per centre for one day of medical treatment. The number of doctors employed in each health centre depends on the size of its catchment area.

Following the 1983 reform, the construction of health centers was carried out quickly (1984–1986) and the equipment they were provided with was initially appropriate for the first stage of their operation. Health centers have in fact fulfilled their objective to increase access to PHC in rural areas at least in part, and they constitute an excellent organizational structure upon which to build an effective PHC service. However due to a number of staffing, financial and organizational problems, their actual performance has fallen short of expectations.

Specifically, most health centers suffer from inadequate staffing, as only 48% of foreseen medical positions were actually filled. It is difficult to recruit doctors in sufficient numbers because of living conditions in rural areas, fewer opportunities for private practice and generally low salaries. Moreover, since 1990 the Ministry of Health has recruited limited numbers of new health care personnel because of a general restriction on employing new public sector employees. The best staffed health centers are those close to major urban areas. The staffing shortages in professions other than doctors, though significant, are somewhat less serious (62% of nursing positions, 55% of paramedical positions, and 62% of administrative staff positions have been filled).

Most doctors working in health centers (roughly 70% of the total) are specialists, as training in general practice was not established until 1987 and is generally inadequate. In addition, health centers have not had managerial and financial autonomy to develop their own policies. They are financed via hospital budgets and they are still administratively attached to district hospitals. They, therefore, have to compete for resources with the hospitals' clinical

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departments, and given their lack of financial autonomy, are not in a position to formulate their own priorities.

Despite these difficulties, there is evidence that health centers are becoming increasingly accepted by the public, and that the flow of rural patients to out-patient departments has been somewhat reduced. About 1500 provincial clinics are administratively attached to health centers and are staffed by publicly employed rural doctors, who, in some cases, are assisted by nurses and midwives. Rural doctors are medical graduates who are required to spend at least one year in a rural area upon graduation. Their lack of clinical experience raises concern about the quality of the services they deliver.

The out-patient departments of public hospitals also fall into the category of NHS-provided PHC. These are a very significant provider of PHC services for urban populations (though of course anyone is free to use these providers). Out-patient departments operate on an appointment basis. All persons, irrespective of type of insurance coverage (or lack of coverage) are entitled to use these services.

PHC provided through social insurance funds

The 1983 legislation had made provisions to include the services and infrastructure of IKA (the largest insurance fund, covering roughly 50% of the population) as part of the NHS. This, however, never took place. IKA and a small number of other insurance funds own and operate their own primary health care facilities, where a number of specialists provide care to fund members that are free at the point of service. IKA offers by far the largest number of fund-owned PHC services through a broad and decentralized network of polyclinics and clinics. Doctors and other health care personnel are employed on the basis of a full- or part-time salary. IKA provides its members with a wide range of preventive, diagnostic and curative services, while most other funds provide a more limited range of services through their own facilities. Services not offered by fund facilities (whether IKA or other funds) are provided by public (NHS) hospitals and private providers, mainly specialists, who are contracted by the funds. Private physicians or diagnostic centers contracted by insurance funds are generally paid on a fee-for-service basis. In the case of remote areas where membership size is small and thus does not justify the construction of IKA facilities, IKA contracts rural doctors whom it pays on a capitation basis. Problems faced by IKA in connection with its PHC services include the following:

High accessibility without significant financial, organizational or administrative restrictions.

Most visits are to specialists while visits to pathologists or family doctors are limited, thus resulting in ineffectiveness as there is no filtering mechanism.

The quality of services is questionable as there are no quality control programs. In a recent survey only four out of ten persons stated that they were satisfied with IKA services, whereas eight out of ten said they would prefer to be members of the Funds for Civil Servants, Bank Employees, or others, where there is full freedom of choice.

There is a limited family physician system, and there is no referral system for hospital care from pathologists to specialists, thus making for lack of continuity in care and lack of guidance for the patient on how to use the health care system effectively.

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Many IKA patients also use private providers on a private basis because they do not trust IKA's health services or because they want a second opinion.

The OGA fund is a special case in that it is financed through the state budget, and its members, being agricultural workers, are provided with PHC services in the rural health centers.

PHC offered through local authorities' services

Some municipalities and communities offer social services (services for the elderly, and prevention and welfare centers), but in addition often provide preventive care and prescriptions. Some of the large municipalities have also begun to establish small clinics. The significance of these services is as yet very small and no data are available that show the aggregate volume of services offered. For example, some data collected for the municipality of Athens indicate that Athens has five consulting centers with 167 doctors of various specialties, 102 additional nursing and administrative staff, and microbiology laboratories.

PHC provided by the private sector Because Greece has a large number of doctors relative to its population, many are obliged to find supplementary professional employment by practicing medicine on a private basis. In addition, dissatisfaction on the part of the public with publicly provided services has led to a large and growing demand for privately provided services. This is confirmed by the high percentage of private health care expenditure in total health care expenditure and by the size of the extensive black economy in the health sector. Today an increasing proportion of doctors, even those working in hospitals or in polyclinics of insurance organizations, maintain a private practice or clinic and offer PHC services.

Doctors in private practice include the following groups:

Doctors employed by the NHS on a full-time basis, who “illegally” maintain a private practice, offering services the cost of which is covered by the patient's personal income (out of-pocket payments).

Doctors employed part-time by the NHS (approximately 300) who also legally maintain a private practice.

Doctors working in polyclinics of insurance organizations (mainly IKA) who also legally maintain a private practice, attracting clients mainly from the insurance funds that employ them. The cost of these services is fully covered by the patients.

Doctors contracted to one or more funds, who work in their private practices and are paid by a fee-for-service system based on fixed prices.

Doctors, who for various reasons cannot or do not want to be contracted to the health funds, providing services on an exclusively private basis. They are paid by the fee-for-service system and prices are determined by market rules. The cost is fully covered by the patients (or partially by private insurance).

Financial streams

The financing flow chart (Figure 3) illustrates the financial and service flows of the Greek health care system. The box on the left hand side represents the population. The three boxes at the top are third party payers which collect contributions, premiums or taxes and reimburse providers as well as patients. The providers of services are represented by the boxes on the right.

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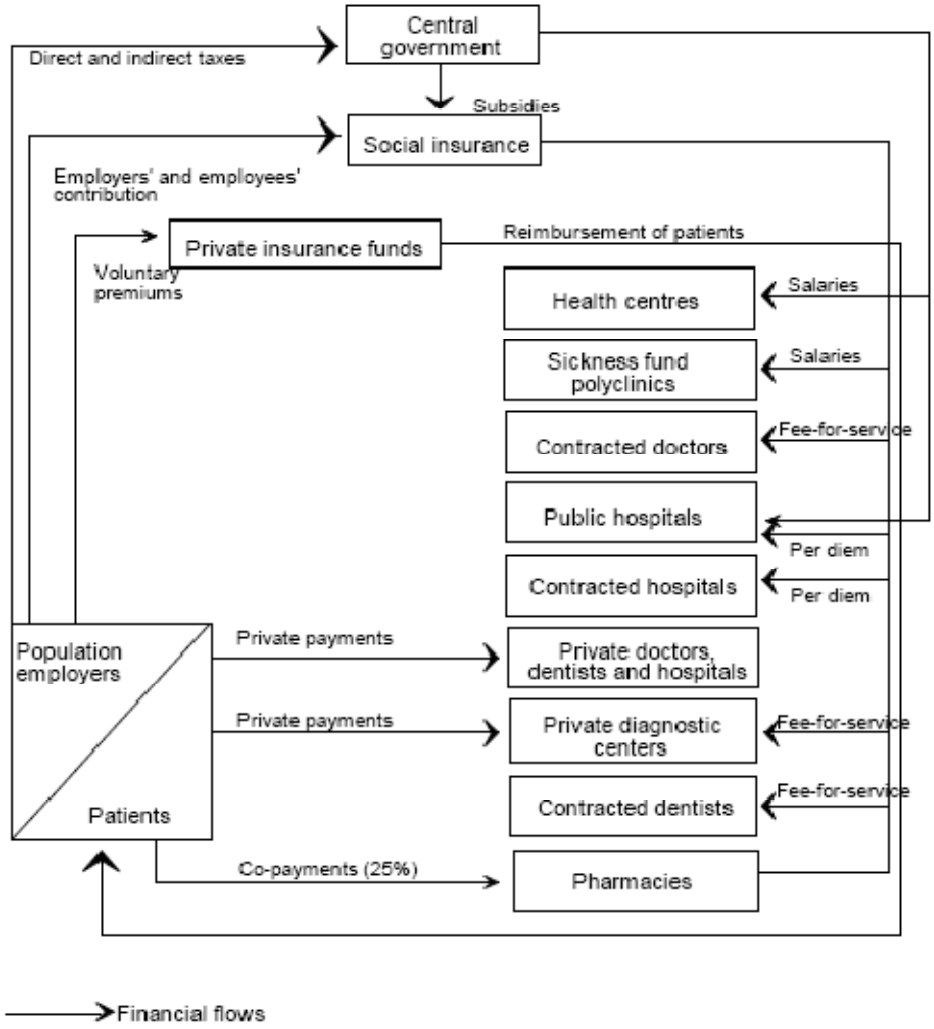

Figure 3. Financial flow chart

The third-party payers are mainly the government and the social insurance funds, as private insurance plays a comparatively small role in the financing of the system. The Greek health care system is a combination of the public contract model and the public integrated model. However, in view of the significant size of out-of-pocket payments, the voluntary out-of-pocket mode of finance and delivery is also relevant in characterizing the Greek system.

Resources for health care are allocated on a historical basis both at the central and the district level, with no other criteria playing a role in determining allocation. The state budget allocation for health is divided between expenditures incurred by the Ministry of Health and Social Solidarity those incurred through the country's 52 districts. Each year, the previous year's allocation is adjusted by an amount equal to the rate of inflation plus new employment and investments. Central level expenditures include expenditures on administration, public health, insurance fund subsidies, subsidies to public hospitals, research expenditure, insurance services to civil servants, etc. The resources allocated through the districts include state administrative expenses for the civil servants employed in the health directorates of the

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districts, and mainly subsidies for public hospitals, health centers, rural doctors, and emergency services in the districts.

Payment of hospitals

Public hospitals are reimbursed by social insurance funds on a per diem basis. Traditionally, per diem fees have been kept below average per diem costs (thus allowing the budgets of social insurance funds to be in surplus until 1993). In 1992 per diem fees were increased by 200% and in 1993 by an additional 600%, thus throwing the insurance funds into deficit. These huge increases were prompted by the conservative government's policy, at that time, to decrease public expenditure on hospitals.

Prior to these increases in per diem fees, only about 12% of hospital revenues came from the fees paid by the insurance funds, with the remaining 88% coming from a state subsidy (this includes payment of salaries to hospital personnel, to be discussed below). At present, the contribution of the insurance funds has increased to about 30% of total hospital revenues. However, this actually resulted in creating significant deficits for the hospitals, as the insurance funds were not in a position to sustain the huge increases in per diem fees.

The state subsidy of hospitals is in principle based on a prospective budget for salaries and investment. However, in practice the state budget pays retrospectively for all hospital expenses incurred excluding sickness fund reimbursement. The system is therefore open-ended and demand-led, containing no incentives whatsoever to encourage cost-containment or efficient practices.

Payment of physicians

All health care personnel employed within the NHS, (i.e. rural health centers and NHS hospitals) are salaried employees of the state. Doctors who work in IKA polyclinics are paid on a salary basis by IKA. Private doctors and dentists who are contracted by the social insurance funds are paid on a fee-for-service basis. The fees are generally set at a very low level, thus providing doctors with the incentive to charge the patient additional fees which are usually paid unofficially.

Unofficial payments to hospital doctors are also a prominent feature of the Greek public hospital sector. Following the introduction of the NHS after 1983, doctors received relatively high salaries. As a result, some progress was made at that time in reducing unofficial payments. However, while doctors now on average receive salaries which are approximately double that of other public employees, these are much lower in relative terms than in the early NHS period, thus creating incentives once again for doctors to supplement their income through unofficial payments. It is estimated that unofficial payments increase doctors' salaries by about 40% on average.

Other health care personnel, especially nurses, are paid salaries which are at roughly the same level as the average of public employees. Quite clearly, payment methods for providers give no efficiency-promoting incentives, and moreover encourage the continuation of the practice of unofficial payments.

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1.5 Sweden

The Swedish health care system is organized on three levels: national, regional and local. The regional level, through the county councils, together with central government, forms the basis of the health care system. The county councils plan the development and organization of health care according to the needs of their residents. Their planning responsibility also includes health services supplied by other providers, such as private practitioners and physicians in occupational medicine.

In 2002, Swedish health care expenditure was 9.2% of GDP. Health care expenditure expressed in US$ PPP per capita was 2517 in 2003, slightly higher than the EU15 average of 2326. The Swedish health care system is primarily funded through taxation. Both county councils and municipalities have the right to levy proportional income taxes on their respective populations. In addition to taxation revenue, financing of health care services is supplemented by state grants and user charges. The social insurance system, managed by the Swedish Social Insurance Agency, provides financial security in case of sickness and disability. No basic or essential health care or drug package is defined within Swedish health care.

The aim of primary care is to improve the general health of the population and to treat diseases and health problems that do not require hospitalization. General practitioners provide treatment, advice and prevention. It is up to each county council to decide how to serve its population with primary care. Primary care is mainly publicly provided. The National Institute of Public Health is responsible for running health promotion and disease prevention programmes at the national level. Preventive and population-oriented health care has been integrated into primary health care.

In Sweden a relatively large proportion of the resources available for medical services have been allocated to the provision of care and treatment at the hospital level. For highly specialized care, Sweden is divided into six large medical care regions, within which the county councils cooperate to provide the population with highly specialized care.

With regard to the training of physicians, the number of medical students is limited, and every year approximately 1100 students join medical training programmes. Medical education is entirely financed by the central government.

Resource allocation principles vary among the county councils. Most county councils have decentralized a great deal of the financial responsibility to health care districts through global budgets. A small group of about five county councils continues to develop per-case payment with expenditure ceilings for some services (primarily hospitals) and capitation models for primary care. The majority of health care providers are publicly owned, and therefore physicians, dentists, pharmacists and other professional groups are mainly salaried employees.

The Health and Medical Services Act of 1982 emphasized a vision of equal health for all. The 1985 DAGMAR reform transferred responsibility for costs of both publicly and privately owned ambulatory health care from the Swedish Social Insurance Agency to the county councils. The main aim of the 1992 ΔDEL reform, the most dominant structural reform of the 1990s, was the transfer of responsibility for providing long-term care to the elderly and disabled from the county councils to the local municipalities. The 1995 Mental Health reform, aiming at improving the quality of life for mental health patients, made the municipalities financially responsible for these patients when they no longer require hospital care, i.e. when they are

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fully medically treated. Following the 1998 Drug reform, the county councils were given full responsibility over costs of prescribed pharmaceuticals. The reform has given county councils direct incentives to increase prescriber knowledge about pharmaceutical costs and existing consumption patterns.

During the late 1990s several reforms were implemented that targeted patient fees: in 1997, the National Drug Benefit Scheme, which regulates copayments on pharmaceuticals for patients, was separated from the cost ceiling for medical treatments. Perhaps the most important reform regarding patient fees was the 1999 Dental Care Reform, which led to the implementation of fixed and nominal subsidies for different types of services, together with free pricing for providers.

Another set of reforms refers to the benefit package. In 1997, county councils were given the right to buy pharmaceuticals for inpatient care directly from pharmaceutical companies. In October 2002, the Pharmaceutical Benefits Board was created, with the responsibility of deciding if a medicine or specific product should be subsidised. With the 2002 New Dental Care Reform, high-cost protection schemes for patients above 64 years of age were implemented. During the early part of the 21st century, the debate on the Swedish health care system has mainly focused on the need for coordination of care, partly driven by county council cost containment. Since 2003, tendencies have been emerging of a recentralization of specialist and emergency care within geographical areas – for example, smaller county councils have started to cooperate on specialist care in larger regions. In 2003, the Parliamentary Committee on Public Sector Responsibilities was formed, with the purpose of analysing the current separation of responsibilities between the three levels of government.

The Swedish health care sector has undergone several important reforms during the past decades. Generally, national reforms that have had an impact on the health care system have focused on three broad areas: the responsibilities of provision of health care services; priorities and patient's rights in health care; and cost containment. The main remaining challenges include cost containment, integration of care and health inequalities.

The health status of the Swedish population is one of the best in the world. The main strengths of the Swedish health care system include a provision of health care services for all based on need, democratic control and local accountability, control over total expenditures and effective management of clinical activities.

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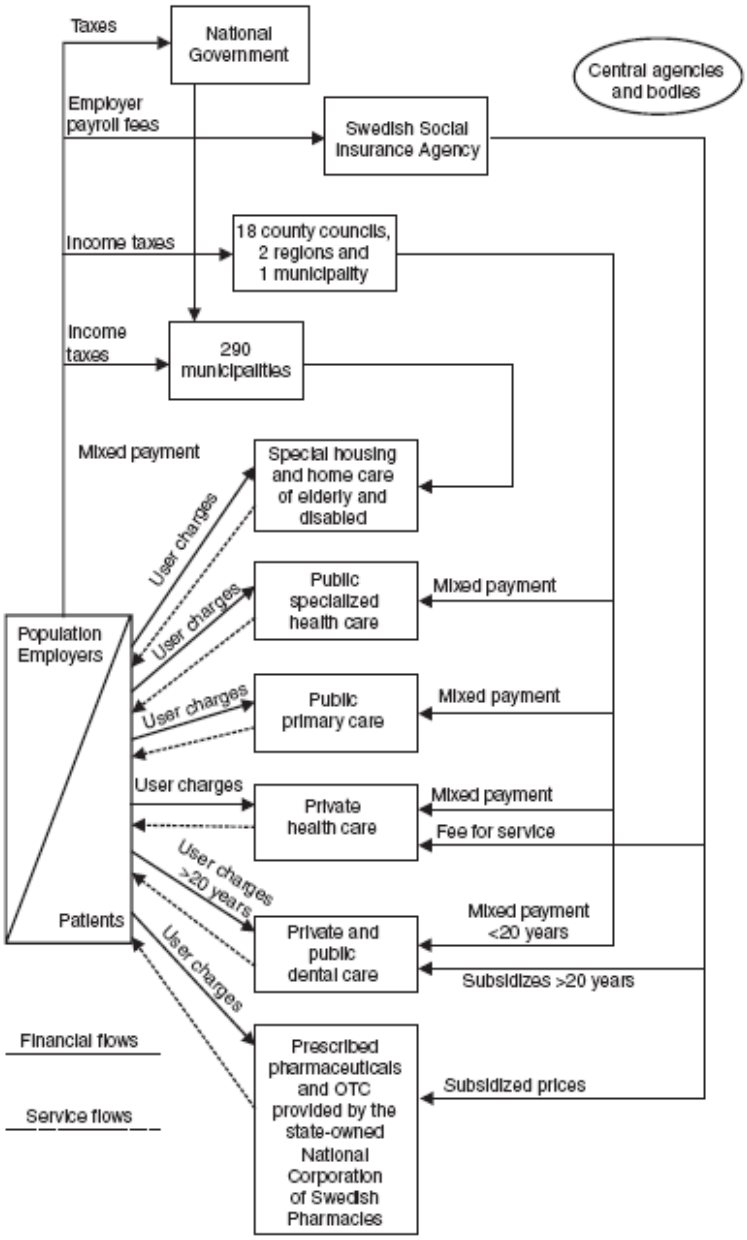

Figure 4. Overview of health system

The health system is primarily funded through taxation. Both the county councils and the municipalities levy proportional income taxes on the population to cover for the services that they provide. The county councils and the municipalities also generate income through state grants and user charges. The mechanisms for paying providers vary among the county councils, but payments based on global budgets or a mix of global budgets and per-capita payments are the most commonly used systems. Physicians and other categories of staff are generally salaried employees.

Health status

The Swedish health care system is a socially responsible system with an explicit public commitment to ensuring the health of all citizens. Life expectancy in Sweden is among the highest of the Nordic countries: in 2003, it was 82.4 years for women and 77.9 years for men. During the past 30 years, the average life expectancy rose by 5.5 years, and Sweden currently has one of the world's oldest populations. Infant mortality decreased substantially during the same period, from 11 to 3 deaths per 1000 live births in 1970 and 2002, respectively. Almost all children had full immunization coverage in 2002 . The drop in immunization coverage for measles between 1990 and 2002 was the result of an increased number of parents rejecting immunization because of possible side-effects. All parents are offered immunization for their children and the downward trend in childhood immunization has now been halted according to the latest public health report (National Board of Health and Welfare 2004a; 2005).

Programmes designed to prevent diseases and injuries have been successful in some cases and, in 2002, the disability-adjusted life expectancy in Sweden was 73.3 years compared to an estimated life expectancy of 80.4 years. Mortality due to diseases of the circulatory system has been significantly reduced during the last 30 years, and this is one of the major factors contributing to the rise in life expectancy. Nonetheless, diseases of the circulatory system accounted for almost half of all deaths in 2001. The second largest cause of death (during the same year) was cancer, although the mortality from cancer has fallen by slightly more than 14% in the last 20 years. Deaths due to mental illness and diseases of the nervous system, eyes and ears increased between 1970 and 2001.

Programmes designed to prevent accidents have also been successful in Sweden. Since the mid-1970s, deaths due to traffic accidents have been reduced by more than 50%. Currently, Sweden, Norway and the United Kingdom have the world's lowest rates of mortality due to traffic accidents. In 1997, the Swedish Government adopted so-called "zero-vision", which implied that there should be no deaths or serious injuries caused by traffic. Work-related injuries and deaths have been significantly reduced during the past 50 years. The decrease has been most prominent in the transport and construction sectors. In 2003, 38 work-related deaths occurred. The number of reported work-related injuries was 6.1 per 1000 working women, and the corresponding figure for men was 8.8 in the same year (National Board of Health and Welfare, 2004a; 2005).

Basic Elements

National level

The Swedish health care system is a regionally based, publicly operated health service. It is organized into three levels: national, regional and local (Figure 4). The regional component, operating through the county councils, together with central government, forms the basis of the health care system. Overall responsibility for the health care sector rests, at the national level, with the Ministry of Health and Social Affairs.

The principal responsibility of the Ministry of Health and Social Affairs (Socialdepartementet) is to ensure that the health care system runs efficiently and according to its fundamental objectives. It prepares cabinet business and deals with policy matters and legislation in health care, social welfare services and health insurance. It allocates financial assistance directed at very specific treatments, and acts as a supervisor of activities in the county councils, e.g. the

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Government may legislate for temporary ceilings on county council and local municipality tax rates.

The National Board of Health and Welfare (Socialstyrelsen), a semiindependent public authority, has a supervisory function over the county councils, acting as the Government's central advisory and supervisory agency for health and social services. The Board supervises implementation of public policy matters and legislation in health care and social welfare services. Its most important duty is to follow up and evaluate the services provided in order to see if they correspond to the goals laid down by the Government. Furthermore, it keeps official statistics on health and health care. The Board includes the Centre for Epidemiology (Epidemiologiskt Centrum), whose objective is to describe, analyse and report on the distribution and development of health and diseases.

All health care personnel come under the supervision of the National Board of Health and Welfare. The Board is also the licensing authority for physicians, dentists and other health-service staff. In addition, the Board is the designated authority under European Community directives for the mutual recognition of diplomas and certificates relating to the health professions.

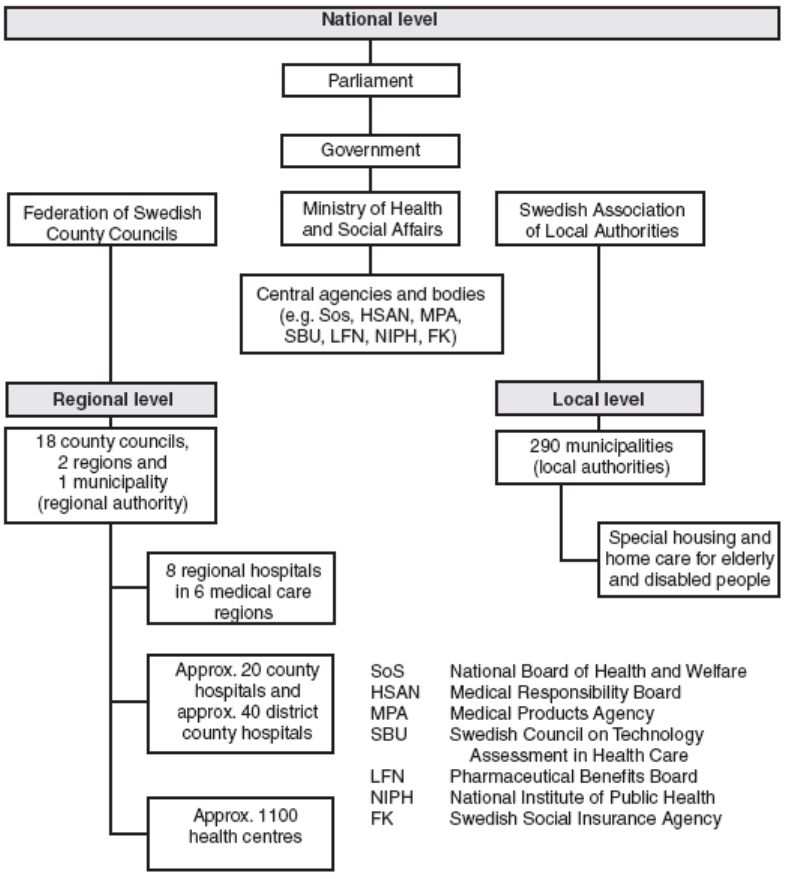

Figure 5: Organizational chart of the statutory health system

The Ministry of Health and the National Board of Health and Welfare collaborate with other central government bodies. The most important are the Medical Responsibility Board (Holso- och Sjukvɛrdens Ansvarsnδmnd, HSAN), the Medical Products Agency (MPA) (Lokemedelsverket), the Swedish Council on Technology Assessment in Health Care (Statens Beredning for Medicinsk Utvordering, known internationally by its Swedish acronym, SBU), the Pharmaceutical Benefits Board (LokemedelsfΦrmɛnsnδmnden, LFN) and the National Institute of Public Health (Folkholsoinstitutet) (Figure 5). HSAN is a government agency that decides on disciplinary measures in the event of complaints or possible malpractice. The MPA is the Swedish national authority responsible for regulation and surveillance of the development, manufacture and sale of drugs and other medicinal products. All drugs sold in Sweden must be approved by and registered with the Agency. The MPA is also responsible for providing information about medicines, giving permission to carry out clinical trials, approving licences and controlling natural remedies and other medicine-related products. The Agency acts both as a formal regulatory authority and as an informal promoter of the rational development and use of new and existing medicinal products. In addition to having national responsibilities, the MPA investigates medicines under consideration at EU level, in collaboration with national drug regulatory authorities in other European countries. All activities of the MPA are financed through contracts and fees, which vary depending on the service provided. LFN is an independent government agency, which started operating on 1 October 2002. The primary task of LFN is to decide if a medicine or product is to be included in the pharmaceutical benefits scheme, and to set the price. It has to give special consideration to cost-effectiveness and marginal utility in its review process. The reason for having a national agency deciding which drugs should be subsidized is that pharmaceutical benefits should be equitable for the entire Swedish population (Pharmaceutical Benefits Board 2002). It is primarily the cost-effectiveness of various products that is assessed, and not the medical indications. However, the Board may make exceptions and decide that reimbursement for a drug should be allowed for a certain indication or subgroup of patients. Thus, LFN may decide to allow reimbursement for a drug for a narrower indication than that for which the drug has been licensed for marketing by the MPA.

The primary objective of SBU is to promote the use of cost-effective health care technologies. SBU has the mandate of the Swedish Government to review and evaluate health care technology from medical, economic, ethical and social points of view. Information on results is disseminated to central and local government officials and medical staff to provide basic data for decisionmaking purposes.

The National Institute of Public Health is a state agency under the Ministry of Health and Social Affairs. It is similar to the national government health departments that exist in many countries, but it reports both to the Minister of Health and Social Affairs and to an independent board of directors. The main tasks of the National Institute of Public Health are to promote health and prevent diseases by providing the Government, state agencies, municipalities and county councils with knowledge based on scientific evidence. It exists to develop and disseminate methods and strategies in the field of public health, to perform cross-sectoral follow-up and evaluation of national public-health policies and to exercise supervision in the areas of alcohol, drugs and tobacco use. The National Corporation of Swedish Pharmacies (Apoteket AB) is a state monopoly that owns all of the pharmacies and thereby maintains a countrywide distribution system. It operates hospital pharmacies under one-year

contracts with the county councils as well as community pharmacies. In 2004, there were 880 pharmacies, of which 80 were located in hospitals. In remote areas, the distribution is covered by approximately 1000 accredited agents, usually grocery stores (National Corporation of Swedish Pharmacies web page 2004- 11-18). The National Corporation of Swedish Pharmacies is responsible for ensuring a good drug supply at uniform prices throughout the country, which means that all approved pharmaceutical products must be available at all pharmacies. In addition, the National Corporation of Swedish Pharmacies is responsible for providing the public and physicians with fact-sheets and other information about drugs.

The Swedish Social Insurance Agency (Forsokringskassan) is the authority that administers the various types of insurance and benefits that make up social insurance in Sweden. Insurance benefits include sickness insurance, parental insurance (leave), a basic retirement pension, a supplementary pension, child allowance, income support and housing allowance. In addition, the Agency's tasks also include work designed to prevent and reduce ill health through positive proactive actionwith the eventual goal of returning the person to the workforce. The Swedish Social Insurance Agency has a regional branch office in each county council which processes individual cases at the regional and local levels. There are also 240 local offices serving local residents. In May 2003 it was decided that the Federation of Swedish County Councils (Landstingsforbundet) and the Swedish Association of Local Authorities (Svenska Kommunforbundet) should be merged into one organization by 1 January 2007. On 1 January 2005, the Swedish Association of Local Authorities and the Federation of Swedish County Councils formed shared headquarters with joint administrative units – The Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Landsting). The Federation of Swedish County Councils is a collaborative nationally oriented organization for the county councils, whereas the Swedish Association of Local Authorities and Regions represents a corresponding organization for the municipalities. The organizations strive to promote and strengthen local self-government and provide local authorities with expert assistance. In addition, they work as the employers' central association for negotiating wages and terms of employment for the personnel employed by the county councils and municipalities. Their activities are financed mainly by members' fees.

Regional level

At the regional level, 18 county councils, two regional bodies (Vostra Gotaland and Skone) and one municipality not belonging to a county council (Gotland) are in charge of the health care delivery system, from primary care to hospital care (including public health and preventive care). The county councils have the overall responsibility for all health care services delivered, and have authority over hospital structure. The executive board of the county council, or an elected hospital board, decides how to organize the management. Executive staff members of the board ensure that health care delivery runs efficiently.

In 1999, two larger regions were formed by the merging of some county councils. For a trial period up to the year 2006, these two regions have been given additional responsibilities, e.g. for the business sector, culture, roads and public transport. These areas used to be managed by the Government, through the county administrative boards (Lonsstyrelsen). Region Skone was established by merging the Kristianstad and Malmohus county councils. Simultaneously, the city of Malmo entrusted the new region with responsibility for health and medical services for its citizens. Vostra Gotaland Region was formed by merging the county councils Skaraborg,

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Olvsborg and Bohus into one region. Vostra Gotaland Region also took over the responsibility of providing health and medical services to the citizens of the city of Goteborg (Palme et al. 2002). The merging of county councils into larger regions has been driven by the increased pressure on county councils to contain costs and to increase efficiency. A similar trend towards hospital mergers can be identified, and traced back to the mid-1990s (Harrison and Calltorp 2000). There is a belief that the merging of hospitals and the formation of larger regions will make the objectives of cost containment and increased efficiency easier to meet.

Primary health care areas consist of one or several primary health care centres. A primary health care area usually has the same geographical area of responsibility as the local municipality, although larger municipalities usually have more than one health care area.

The county councils are grouped into six medical care regions (the Stockholm Region, the South-Eastern Region, the Southern Region, the Western Region, the Uppsala–Orebro Region and the Northern Region). These regions were established to facilitate cooperation in tertiary care among the county councils. Each region serves a population averaging more than 1 million people. According to the 1982 Health and Medical Services Act, the county councils are required to provide for and promote the health of their residents and to offer equal access to health care. They also need to plan the development and organization of health care according to the needs of their population and the resources given.

The county councils also regulate the payment of private health care providers. A private health care provider must have an agreement with the county council in order to be reimbursed from social insurance. County councils regulate the establishment of new private practices and the number of patients that private practitioners can see during a year. If the private provider does not have any agreement or if the private provider does not use the regulated fee schedule, the provider is not reimbursed and the patient will have to pay the full charge to the provider.

Local level

At the local level, there are 290 municipalities with their own areas of responsibility. The population varies from less than 3000 to approximately 760 000 individuals. The traditional organization of the municipalities involves a municipal executive board, a municipal council and several local government committees. The municipal executive board leads and coordinates the entire municipality's business and acts as a supervisor for the committees. The board is responsible to the municipal council for following up matters that might influence the development and economy of the municipality. The municipal council's duty is to make decisions about taxes, goals and budgets for all community-run businesses, and about the organization and tasks of the committees. The municipalities are members of the Swedish Association of Local Authorities, which is a collaborative nationally oriented organization that aims to promote and strengthen local self-government and to provide local authorities with expert assistance.

The responsibilities of a municipality include issues relating to the immediate environment of the citizens, e.g. schools, social welfare services, roads, water, sewerage, energy, etc. Besides providing financial assistance, social services in Sweden cover child care, school health services, environmental hygiene, and care of the elderly, the disabled and long-term psychiatric patients. Patients who have been fully medically treated and have been discharged

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from acutecare or geriatric hospitals also fall within the remit of the municipalities. The municipalities operate public nursing homes and home care. The social services employ a large number of staff – 215 000 in 2001 – and about 90% of them work in care and nursing for the elderly and disabled. The workforce in the social services sector is strongly dominated by women (90% in 2001) (Swedish Association of Local Authorities 2004).

Decentralization and centralization

Sweden has a long tradition of local self-government. The responsibility for health care is decentralized to regional and local governments, with the exception of overall goals and policies, which are determined at national level. The political responsibility for the financing and provision of health services lies with the county councils, whereas local municipalities are responsible for delivering and financing long-term care for the elderly and the disabled, and for long-term psychiatric care. Both the county councils and the municipalities have the right to levy proportional income taxes on their populations to finance these activities. The local municipalities are not subordinated, or accountable to the county councils.

The process of decentralization has been dynamic. There has been constant oscillation between centralization and decentralization in Swedish health care organizations (Axelsson 2000). Decentralization of responsibilities within the Swedish health care system does not only refer to legislative devolution between central and local government, but also to decentralization within each county council. Since the 1970s, financial responsibility has been decentralized within each county council, and the degree of decentralization, organization and management varies considerably among county councils. By the end of the 1970s, it was evident that county council revenues would not increase at the same pace as before, and cost containment became an important issue. Furthermore, the expansion and differentiation of the sector had made it difficult to plan and manage the provision of health services by means of detailed long-term plans of counties. Incentives that would increase productivity and efficiency became important elements in the future development of planning and management systems. Generally, several local health care districts within each county council were formed, each having overall political responsibility for the health of its residents. In the 1980s, global budgets were introduced. Districts became responsible for resource allocation within their geographical areas, and central county councils managed the allocation of the budget among the districts. Many districts, most of which managed a hospital and several primary health care centres, started practising the same principles of global budgeting within the district. Financial responsibilities were decentralized to hospital department and primary health care centre levels. The professional heads of department were cost-liable for their activities. This can be seen as a shift in focus – from politicians to professionals – with respect to the planning of health services. Another interpretation is that it gave the politicians at local level more comprehensive responsibility.

The introduction of global budgeting and cost centres was not sufficient with regard to efficiency and cost containment. Although the system performed well with respect to cost containment, productivity was still considered low. In the late 1980s, cost-centre management was accordingly replaced with systems of transfer pricing; health-service providers were to be reimbursed through prospective per-case payments instead of through activity budgets. Today, payments to both hospitals and primary care centres are based on global budgets in about 50% of the county councils. Among the others, a smaller group of about five county

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councils continue to develop per-case payment with expenditure ceilings for some services (primarily hospitals) and capitation models for primary care. In another group of a similar size, payment for primary care has been moved in the direction of capitation, whereas global budgets are used for all other services.

Most health care facilities are owned and operated by the county councils. There are few private hospitals in Sweden, and the numbers of private physicians and health centres vary widely among the county councils. In some urban county councils, up to 60% of primary care physicians may be private practitioners, whereas in other county councils only a few private practitioners can be found. The proportion of practitioners employed by private providers increased from 14.9% to 17.5% between 1993 and 1999 (National Board of Health and Welfare 2002b). The same variation in the public/private mix of providers can be found across municipalities. In total, the proportion of elderly people receiving nursing-home care or home-help services from private providers contracted by municipalities increased from 5.1% to 10.6% between 1994 and 2002 (National Board of Health and Welfare web page 2005-01-17).

Financial Streams

The funding of the Swedish health care system is primarily through taxes. Both the county councils and the municipalities have the right to levy proportional income taxes on their respective populations. The financing of health care services by local taxes is supplemented by the Government and by user charges. Subsidies for dental care and prescription drugs are paid for by national social insurance, and the Swedish Social Insurance Agency generates revenues primarily through employer payroll fees (see Fig 2). As the financial and political responsibility for health care is decentralized to the county councils, it is difficult to make precise connections between the sources of finance and different activities within the county councils. This is because most county council activities are financed through county tax revenues, and because the county councils are also responsible for other activities, e.g. education and cultural activities. In 2003, the total cost for the county councils was SKr 149 billion, of which approximately 92% was directly connected with health and dental care (Federation of Swedish County Councils 2004b). The corresponding figures for the municipalities in the same year was SKr 389 billion, of which approximately 30% was directly connected with care for the elderly and the disabled (Swedish Association of Local Authorities 2004).

Revenue mobilization

County council revenue mobilization is heavily dependent on tax income. In 2003, 72% of the county council revenues originated from local taxes. The remainder consisted of: state grants, 18% (subsidies and general state grants), user charges, 3% and other sources, 7% (see figure 6). Note that the figures describe total county council revenues and not total expenditures on health. In 2003, 92% of the total county council expenditures were directly connected to health and dental care services. The municipalities also generate the major part of their revenues through local taxes (69% in 2003). Expenditures on care for the elderly and disabled constituted 30% of the municipalities' total expenditures in the same year (Federation of Swedish County Councils 2004b).

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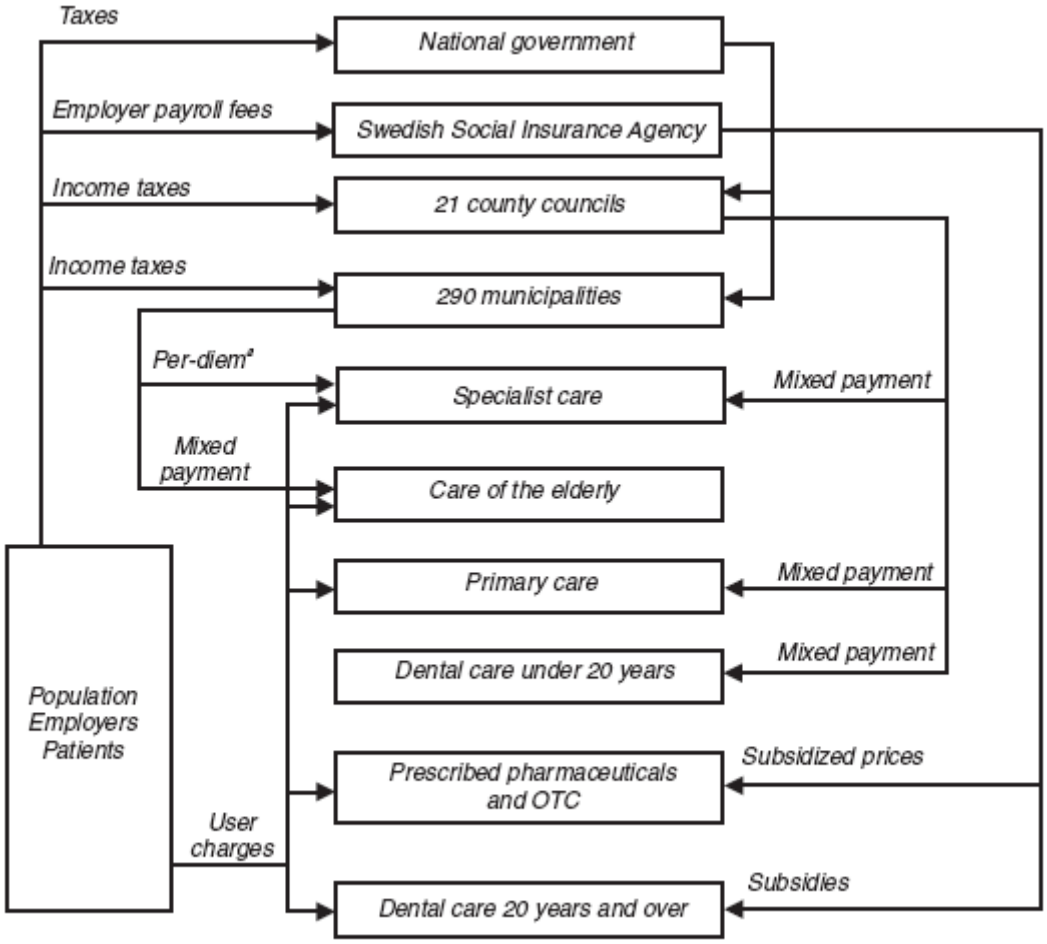

Figure 6: Financial flowchart of the health care system

The main source of finance has been quite stable over time. Taxes, as a proportion of total county council revenue, increased from 62.3% in 1980 to 72.2% in 2003 (Federation of Swedish County Councils 2004b). During the last 5 years, user fees as a proportion of total revenues decreased by 0.6%, whereas local taxes increased by 3.7%. With the exception of taxes, comparison of sources of revenue with periods before 1998 is not possible, since the reporting of data has not been consistent.

1.6 Norway

The development of a public health care sector

The first professional and official health care system consisted of a network of general practitioners who practised out of their own offices or in the homes of their patients. The first practitioners established themselves during the latter part of the eighteenth century. It was not until the middle of the nineteenth century that the population-to-doctor ratio passed 5000:1. Norway was industrialized comparatively late and doctors and other medical personnel were rare in rural areas. The majority of the first doctors were public officials, and

from 1836 onwards, they were called district physicians. From about the middle of the century, some municipalities also hired physicians who had the obligation of caring for the sick poor. Hospitals started to become institutions to cure the sick around the turn of the century. The fact that the country remained poor and that the majority of the population lived in rural sparsely-populated areas was reflected in the health care system into the twentieth century. Historically, the municipalities and local government had strong traditions, a fact which is currently reflected in an egalitarian and locally-oriented culture.

A decentralized model of provision of welfare goods and services

The years following the Second World War can be described as a continual process of reform in the relationship between state and local government. This process of reform was present in health and social care, as well as in other sectors. The goal has been to find an acceptable balance of power between these two levels of government. There has been an ongoing process of devolution of central powers to local governments, aimed to focus as much as possible on the municipal level. The philosophy behind this is that decentralization is an expression of applied democracy. It brings decision-making closer to those who are affected and promotes popular participation in local political affairs. Moreover, it is believed that delegation of authority usually leads to simplification of administrative procedures. The central authorities are responsible for national policy, for drawing up general guidelines, for advising, and for ensuring that services offered comply with national goals. Maintaining the principle of equal access to public service is a critical role of the central authorities in a decentralized system. Regarding decentralization, the 1992 Local Government Act replaced an earlier legislative piece passed in the mid-1950s. The new act did not, in fact, introduce significant changes within the health care sector. Actually, the philosophy which underlies the territorial division of powers has changed little during the second half of the century: the purpose has always been to enable counties and municipalities to take over service provision by defining a clear division of responsibility between the central government and the municipal and county authorities. The administrative level which is responsible for implementing various services has also been made responsible for their financing. In order to cover expenditures, the municipalities and counties draw on local taxes in addition to block grants and earmarked grants from the state for high priority reforms. To a large extent, the central government and the parliament determine counties' and municipalities' fiscal situation and annual transfers.

The responsibility of the municipalities

The Local Authority Health Care Act was passed in 1984 and made local municipalities responsible for all primary health care. This marked the end of the old, central government appointed district medical officer, an institution established in 1860. For a long period, responsibility for health care (at the local level) had been divided among different administration levels: municipalities, counties and the state. Even responsibility for some single services was placed on different levels. Such a division of tasks and responsibility made the organization unclear and difficult to supervise. For example, the public medical service, offered by district medical officers, was the responsibility of the state, but services offered by district midwives were the responsibility of the counties. Especially in the period after 1975, and as a result of the creation of the health regions, a growing number of actors became involved in the provision of local health care services. Most importantly, there was a need for collaboration among heath services, social services and the National Insurance System (NIS),

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which was created in 1967. Different schemes were attempted in order to solve problems of collaboration and coordination. A variety of different acts spelled out the municipalities' responsibility. According to the Act on Local Authority Health Care (1984), the Act on the Protection of Children (1992) and the Act on Social Services (1991), the municipalities are responsible for preventive efforts and for providing and financing most primary health care and social services. The rights in these laws also apply to people with mental problems. The law leaves a large mandate for local health care services to take part in shaping the local social structure. In 1987, the act was extended to include environmentally-oriented health activities. In 1988, the task of managing nursing homes was shifted from counties to municipalities, and the responsibility of local health care authorities was further increased in 1991, when care of the mentally disabled was added to their charge (for more detail, see the section on Organizational structure and management).

The responsibility of the counties

Regarding specialized care, there was no general act regulating the hospital sector until 1969, when the Hospital Act was passed. Until this time, during the 1960s, Norwegian health care consisted of piecemeal organization, uneven financing, poor coordination and an unclear delegation of responsibility. The Hospital Act introduced a unified system for all medical institutions, making the counties responsible for planning, building and managing hospitals in order to meet the needs of their respective population. Since the adoption of the Act, each of Norway's 19 counties has assumed responsibility for the financing, planning and provision of specialized health care. In 1974 the White Paper, Hospital Development in a Regional Public Health Service, put an overall fundamental strategy of health services into a regional perspective. The country was divided into five health regions, each with a regional teaching hospital. The purpose was to establish a uniform structure and an organizational framework that, on one hand, ensured equal access to health, and, on the other, allowed for better control over resources and more effective resource allocation. The main characteristics of this organizational structure are described in the next section.

Basic Elements

The organizational structure of the Norwegian health care system is built on the principle of equal access to services. All inhabitants of the country shall have the same access to services, independent of social status, location and income. To fulfill this aim, the organizational structure has three levels following the political tiers described in the previous sections: the central state, county and municipalities. While the role of the state is to provide national health policy, to prepare and oversee legislation and to allocate funds, the main responsibility for the provision of health care services lies with the 19 counties and the 435 municipalities At the national level, the parliament serves as the political decision-making body. The Ministry of Health and Social Affairs is the executive body withspecial responsibility for:

- legislation
- capacity expansion
- budgeting and planning
- information management
- policy design.

The Ministry of Local Government and Local Authorities is responsible for the distribution of block grants from the state. These grants are allocated according to a formula including the age/sex composition of the population, demographic indicators and variables related to health needs (e.g., mortality rates). While responsibility for the provision of services is decentralized, both the regulation and supervision of services are the responsibility of national authorities. In addition, the central government directs the National Institute of Public Health, some research and prevention councils such as the Council on Smoking and Health and the Council on Nutrition and Health, and several research institutes (e.g. the Cancer Registry of Norway). The central authorities also remain in ownership of some hospitals, such as the Norwegian National Hospital (Rikshospitalet). There is also The Norwegian Board of Health, an independent professional body which, in collaboration with nineteen county medical officers, is responsible for promoting quality and legal safeguards within the Norwegian health sector. Administratively, the Board of Health is an autonomous agency, and therefore is not hierarchically subordinated to the Ministry for Health and Social Affairs. Its main areas of responsibility are as follows:

• supervision of all health services and all health personnel

• administrative tasks associated with supervision (e.g., dealing with complaints)

• advice and guidance on health matters to the Ministry of Health and SocialAffairs, the health sector and the general public.

The operational framework of the Board of Health and the county medical officers is based on four strategic areas: quality improvement; legal clarity and consistency; collection and analysis of data; and dissemination of experience. The Board of Health has a total of 154 posts; the offices of the county medical officers consist of 307 posts.

The next level down in Norway, the counties, are too small for efficient and cost-effective provision of high quality specialized health services. Duplication of services within relatively small geographic areas and the provision of acute care at most local hospitals both reduce patient volume and make for inefficient use of health care resources, including health care personnel. For these reasons, it has been a national aim over the last 25 years to organize and plan specialized health care services within larger geographic areas. With this objective, in 1974, Norway was divided into five health regions. Each health region consists of three to five counties. To ensure planning and cooperation, regional health committees have been established in each region. Members of the regional committees are politically appointed representatives from each county in the region. So far, the impact of the regional health committees has been limited. Early in the 1990s, the national authorities tried to revitalize the regional health committees by giving them an advisory function regarding cooperation and division of tasks among county and national hospitals (St. meld. nr. 50, 1993–94). By asking the regional health committees to prepare health plans, the parliament hoped to strengthen the regional integration of hospital services. In the first regional health plans which were developed, the need for greater efficiency and for restructuring the hospital sector was unanimously recommended. Beginning in the year 2000, each region is legally obliged to submit plans for approval to the Ministry of Health and Social Affairs. These plans are strategic documents intended to show how the regions aim to fulfill national health policy goals (see the section on Health care reforms). As mentioned, Norway's 19 counties are responsible for the financing, planning and provision of specialized care. This includes both general and psychiatric

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institutions, as well as other specialized medical services, such as laboratory, radiology and ambulatory services, special care for alcoholics and drug addicts, and dental care for adults. The country's 435 municipalities, whose size varies considerably, are responsible for the provision and financing of primary health care and social services. The Local Authority Health Care Act defines the responsibilities of the primary health care services and patient rights. All citizens have the right to satisfactory health care, accessible in their local community. Regarding primary care, municipalities must organize and finance services for disease prevention and health promotion, diagnosis and treatment of illness, and rehabilitation. This includes care for the mentally ill, alcoholics and drug addicts. In addition, each county must provide services for disease prevention and dental care for children under 18 years of age. Municipalities are also responsible for social services, including the provision of care for the elderly and the disabled, continuous care residences (nursing homes, etc.), social support and leisure activities, day-care centers, and social security benefits. Regarding mental health, the municipalities play a key role in the provision and coordination of services to people with psychiatric problems. However, services provided are still lacking in several respects. There is a scarcity of resources, insufficient knowledge of needs, and a lack of solutions. The central government has actively encouraged local planning, coordination and expansion in this area. In the latter part of the 1990s, special attention has been given to people with serious mental problems, requiring coordination of services over a long period of time. Making individual plans, which coordinate necessary services, has now become a mandatory task for the municipalities and a legal right for patients. The main political body is the municipal council, which is elected for a period of four years. In addition to primary health care and social services, municipalities are responsible for cultural activities and primary education. In most municipalities, a political body together with an administrative officer manage both health care and social welfare services. Generally speaking, each municipality usually has three separate administrative departments: for medical care; nursing and home care; and social welfare. Many of the medical services are located in health centers, often including physicians in joint practice No minimum requirements for physician-patient ratios or provider mix are given, so the municipalities are free to decide whether to employ family doctors and other health care staff directly, or to contract-out services with private physicians. The formal role of the counties and municipalities was strengthened in 1980 with the introduction of a capitated (block grant) financing system. The rationale for the division of tasks between these two levels of government is based on economies of scale and the principle of subsidiarity: services are attributed to municipalities unless it is significantly more efficient for them to be provided at a higher level (e.g., counties) due to economies of scale. Initially, counties and municipalities received earmarked block grants for each type of service. From 1986 onwards, however, under the block grant scheme, municipalities were allowed to prioritize different types of services. By giving local authorities both the autonomy to set the level of service provision and the economic means to provide the services, the aim was that this decentralized model would provide a more efficient service provision and serve local needs better than a centralized model. During the 1990s, the role of central government changed. The focus has turned to problems of effectiveness and quality of services, particularly in the hospital sector. This has led to major reforms in the financing system as well as legislation on patient's rights. A hospital financing system that modifies the block grant system and includes prospective, activity-based revenue was introduced in 1997. The Patients Right Act will be implemented in 2000, while The Hospital Act will be modernized and replaced in 2001. A primary care reform introducing a

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family doctor will come into force in 2001. The grant system was modified by partly reimbursing counties on the basis of a earmarked fee-per-patient scheme. This has led to growth in the share of health care expenditures that are covered by central authorities (see the section on Health care finance and expenditure). The intention behind the hospital financing reform was to increase activity and reduce hospital waiting lists. In 1998, the share of hospital expenses (including outpatient activity) financed from the fee-per-patient-scheme was 41% and the share financed by the counties was 43%. The remaining 14% was financed partly by user fees and partly by general grants from the central government. There is also a substantial flow of funds from the central government to the counties to cover investment costs for medical equipment and the cost of the major increase in the capacity for delivering psychiatric health care services initiated in the 1990s.

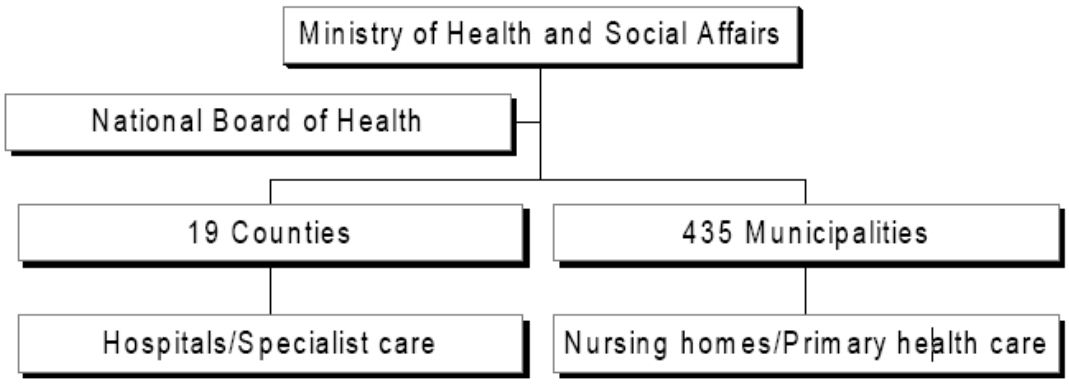

Figure 7. Organizational chart

Planning, regulation and management

The Norwegian system of health care delivery is almost a fully integrated system. Most hospitals (somatic as well as psychiatric) are owned and managed by public authorities. Presently, they are organized as public institutions within the general framework of the county level bureaucracy. Thus, hospitals are bound to the legal framework of public services, with their emphasis on stability and accountability. Most hospitals have boards appointed by the counties. Their formal position is often weak and, thus, they are bypassed in communication between hospital directors and the counties. The counties are free to decide whether to appoint a board or not, as there are few regulations concerning the internal organization of hospitals. In the market for hospital services, there is no purchaser/provider split. However, there is an ongoing debate concerning the formal organizational framework of the public hospitals, including discussion as to whether hospitals should be made into trusts. This will be discussed in the section on Health care reforms.

For physician services outside of hospitals, including both specialized and general services, there is a contract-based market. Specialists outside of hospitals are private, but they can enter into a contract with the county. Under this contract, they become part of the county's health plan and receive a general grant from the county, a fee-for-service payment from the National Insurance System (NIS), and a fee-for-service payment from the patients. Specialists

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who do not enter into such contracts are not part of the county health plan and must generate all of their income from their patients. General practitioners are either salaried by the municipality or are contracted out by the public system. Contracted-out general practitioners receive a combination of fee-for-service from the NIS, and a general grant in order to perform their services.

Responsibility for providing services is decentralized to counties and municipalities, but there are large elements of centralized planning. Broad guidelines for priority setting are found in official documents. Regional health plans have to be authorized by the Ministry of Health and Social Affairs. To assist the ministry in the distribution of physicians, there is a National Council for Education of Specialists. This council has representatives from the counties, the universities, the health regions and the Medical Association (figure 7).

The number of pharmacies is centrally regulated, and licences for operating a pharmacy are issued by the Norwegian Board of Health (NBH). The National Medicines Control Board sets maximum prices on pharmaceuticals. All pharmaceuticals, both prescription and non-prescription, are sold in pharmacies. Health personnel are licensed by the Chief County Medical Officer in Oslo. Unlicensed personnel cannot practice. Personnel are educated in public colleges or public universities. Personnel with a foreign education may apply for a licence in Norway. In the past decade, a growing emphasis has been placed on the formal rights of the users and the different involved parties in the decision making process, both when it comes to planning and law making. The involved parties are often represented as members of public commissions or in the planning process itself. All reports made by royal commissions, bills presented to parliament, public health plans, etc. are subjects of a broad hearing by all involved parties. This includes patients' (users') organizations, professionals, other public agencies and administrative levels. The results of the hearing are to be presented to the appropriate decision making body.

Decentralization of the health care system

There has been considerable debate about the merits of Norway's decentralization, in particular with respect to somatic hospitals. There is large variation among counties regarding use of hospital services, as well as in medical practice. Decentralization has led to problems of coordination of services and accountability. The existence of three administrative and political tiers has sometimes led to a lack of willingness/ability by the local authorities to take financial responsibility. Soft budgeting prevails and there are frequent incidents in which local authorities claim that their financial ability to provide a set of services demanded by central regulation is limited. Lack of coordination also tends to lead to situations in which patients in need of primary care remain in hospitals (somatic and psychiatric) because there is no capacity in the municipalities. The large number of decision-making units leads to duplication of services, and a simultaneous problem of over-capacity and waiting lists.

Health care finance and expenditure

Main system of finance and coverage

The most important feature of the Norwegian health care system is the predominance of tax-financed public provision. The whole resident population of Norway is covered for needs and

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the financial burden of using health care services. As there is no premium-based financing, there is only a small connection (limited to out-of-pocket payments) between individual health risks and costs. Thus, the health care system is financed through taxation and out-of-pocket payments. In addition, different political actors play a role in the intermediate financing flows: national government, the counties and the municipalities (with the right of taxation, in addition to central state taxation), and the National Insurance Service (mainly fee-for-service financing in health care).

Although Norway is formally a unitary state, the principle of subsidiarity is followed. Central government has overall responsibility for laws and regulations in most policy sectors, including health and social services, as well as for regulating local taxation. Municipalities are responsible for primary care and treatment, along with primary schools, and basic infrastructure, while counties are responsible for specialized medical care and treatment, such as hospitals and outpatient specialized treatment, in addition to college education, roads, and communication, etc. The system of block grants from central to local government (counties and municipalities), introduced in the 1980s, is an important element of subsidiarity.

Fig. 2 illustrates some of these intermediate financing flows in the health care sector. Block grants from the central government to the municipalities and counties are not classified as financing by the state, but by local government. The reason for this is that block grants are meant to be a source of financing for local activities in general (education, local infrastructure, health, etc.). It is in the local government's own sphere of authority to prioritize among the different services. The figure shows that the provision of health care is among the most resource-consuming responsibilities of the counties and municipalities. The proportion of public health financed by counties has been reduced from about 40% at the end of the 1980s to less than 30% in 1997. The proportion of statefinanced expenditure has increased to more than 50% at the end of the 1990s (see the section on Financial resource allocation). There are significant crosscounty flows of patients, in particular into the regional teaching hospitals. There is also a price system through which the county where the patient resides compensates the county where the patient is treated. The role of the local levels – municipalities and counties – in the delivery of health care services is important, and there have been almost no changes in the total proportion of financing allocated through local government in the period from 1980 to 1997. Counties' financing has been reduced in favour of municipalities because of the transfer of care of the elderly in 1988 and of care of the mentally handicapped in 1991 from the former to the latter. The share of the municipal expenditure (including Oslo) devoted to health and social care is about 43% and almost has not changed between 1991–1997. The share of the counties' expenditures in 1996 devoted to somatic specialist health care was 41%; psychiatric care was 9%.

In addition, some parts of the health care sector – mainly pharmaceuticals, fees of private contracted-out doctors and transportation – are financed through the National Insurance System. Approximately 15% of total public health care expenditure is channeled through the NIS. It acts therefore as a third payer, channeling funding derived mainly from taxation through the health care organization to providers.

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Health care benefits and rationing

The Norwegian health care system includes universal access to a wide range of benefits, consisting of most preventive and curative services. However, some services are excluded from the statutory health system, such as adult dental care and spectacles.

Pharmaceuticals are divided into three categories. Non-prescription medicines are fully paid for by the individual; prescriptions are either covered by the NIS ("blue prescriptions") or paid for in full by the patient ("white prescriptions"). There is a co-payment on blue prescriptions which is limited to 36% of the prescription fee. In 1999, there was a ceiling of NKr 1320 per year, or US $65 on all co-payments, including co-payments for outpatient care or primary care. Patients in hospitals do not pay anything for medication.

Complementary sources of finance

The National Insurance Scheme

All residents of Norway or people working in the country are insured under the National Insurance Scheme (NIS). The compulsory insurance coverage is also maintained during a temporary stay abroad (for less than one year). If a person accepts paid work abroad, however, the insurance coverage is terminated. The NIS is financed by contributions from employees, the self-employed and other members, employers' contributions and state funding. Contribution rates and state grants are determined by the Parliament.

Persons insured under the NIS are entitled to the following benefits: elderly, survivors and disability, basic care in case of disablement, rehabilitation,occupational injury, single parents, monetary reimbursement in case of sickness, maternity, adoption and unemployment, health care, and maternity and funeral expenses. Disability benefits comprise basic benefits, care benefits and disability pensions. Rehabilitation benefits are granted if the person concerned has a permanently reduced work capacity or substantially limited opportunities in choice of occupation or place of work. Benefits are also granted for improvements in general functional capacity if this has been substantially reduced due to illness, injury or defects.

As can be seen, the NIS covers a great deal of risks related to foregone income and expenses. The total expenses of the NIS in 1998 were NKr 145 250 million. The amount represents more than 35% of total public expenditure and approximately 13.2% of GDP. About one third of its 1998 budget (44 703 million NKr) was derived from a specific component of tax revenues paid by employees (called Membership of Social Security), while the other two thirds came from employers' payroll contributions (61 696 million NKr, 42% of the total) and general taxation (about 40 000 million NKr, 27%). The major components of NIS expenditure consist of the elderly pension system (58 000 million NKr in 1998) and the pension system for the disabled (28 000 million NKr), while health care expenditure by the NIS represented almost 15 000 million NKr in 1997. About 1.2 million Norwegians are Social Security recipients; specifically, 7% of Norwegian men and 12% of women have social security payments as their main source of income.

Out-of-pocket payments

The entitlements of medical benefits during sickness and maternity are partially covered by the NIS. All insured persons are granted free hospital treatment and coverage, including

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medicines. This follows from the provisions of the Hospital Act (1969) and the Act on Mental Health Care (1961). There are no out-of-pocket payments in Norwegian hospitals.

In the case of secondary care (specialist care but provided outside of the hospital), the provisions of the Local Health Care Act (1984) and the National Insurance Act (1967) apply. Patients are charged NKr 135 (US $17) for each visit to a hospital outpatient clinic. There are also co-payments for laboratory tests, X-rays and some pharmaceuticals at the outpatient clinics. The patient has to pay a share of the cost of treatment by a general practitioner or a specialist outside the hospital, for treatment by a psychologist, for prescriptions of important drugs, and for transportation expenses in connection with examination or treatment. The municipality and/or the NIS cover the majority of the expense. For example, the cost-sharing amount for an adult in connection with treatment by a general practitioner is NKr 102 (US $13) for each consultation, and 36% of the expense of important medicines (maximum NKr 330 (US $41) per prescription). For refills on prescriptions, a new cost-sharing amount shall be paid when a supply equal to three months' consumption has been received. There are certain exemptions from cost-sharing for special diseases and specific groups of people.

A ceiling for cost-sharing was introduced in the early 1980s. The ceiling is fixed by the parliament for one year at a time; for 1999, it was fixed to NKr 1320 (US $165). After the ceiling has been reached, a card is issued giving entitlement to free treatment and benefits, as mentioned, for the rest of the calendar year. Cost-sharing amounts for children under the age of 16 are included in a parent's ceiling. Children under the age of seven are exempted from cost-sharing for treatment given by physician or physiotherapist, certain medicines, and travel expenses. Necessary medical examinations during pregnancy and after recovery from delivery are free. In the case of home delivery, a birth allowance of NKr 1765 (US $221) is granted. Municipal services, like home care of the elderly and disabled and inpatient care of the elderly, are among the services which are not included in the ceiling for cost-sharing by the NIS. Dental care and spectacles are mainly financed by out-of-pocket sources by the user.

The out-of-pocket payments in private health care, that is, for services given by physicians without a contract with local authorities (see the section on Financial resource allocation) are not subject to price regulation. Out-of-pocket payments in publicly provided health care. According to these estimates, made for 1993, about 10% of public health care expenses consist of out-of-pocket payments by patients and users. Dental care and out-of-pocket fees for inpatient care of the elderly and handicapped are the main areas of private financing.

Financial Streams

The size of the overall health care budget is the result of decisions made at state, county and local levels. Thus, in principle, this budget may vary from year to year depending, among other variables, on priorities set at the different administrative levels. In practice, however, both county and municipal budgets are very stable.

The size of the public health care budget will generally be the result of a political process from below in which county councils or municipal councils allocate their (stipulated) resources to the different services they provide. In some cases, it has been speculated that local governments tend to allocate less resources to health care in order to obtain extra funds from the central government. There is also scattered evidence that such tactics have been successful. The implementation of a case-based payment system for hospital services has been

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discussed for a long time as a solution to this problem. In 1997, in fact, a partly activity-based financing system for hospital services was introduced. One of the results of this change is that state financing has increased, amounting to around 50% of total hospital costs in 2000. Regarding the other 50%, counties use their tax incomes and their block grants from the state to finance 43% and the remaining 7% is generated from such income as user fees, rents, etc.

The Norwegian system is a decentralized system where the state level allocates funds to the county and municipal levels without directly interfering with resource allocation. The local health care services are financed through a combination of government revenues, retrospective reimbursement by the NIS, and out-of-pocket payments by the patients. The municipalities and counties receive block grants from the central government which complement local revenues from taxes and charges. Funds are allocated by the central state to local governments on a capitation basis, and demographic variables (age/sex composition etc) are used. While both counties and municipalities formally have considerable discretion in resource allocation, the need to adhere to central regulations severely reduces this freedom in practice. Thus, it has been argued that central law and regulations make local autonomy less real than it seems to be on paper (figure 8).

High priority reforms in local government, for example, like investments in nursing homes, abolishment of institutions in psychiatric care, and investments in care facilities for the mentally handicapped, are often partly financed by the central government for an initial period through earmarked funds which supplement the block grants to local government. There has been a great deal of political debate linked to the question of earmarked funding versus block grants. This issue is discussed in greater detail in the next section. Capital investments are financed from different budgets than operating expenses and on an ad hoc basis. Medical equipment is funded partly by the central government and partly by the counties. Central grants are not available, however, until the county has paid its share. Capital developments for nursing homes and home health care units are subsidized by the state and, in some cases, building such units is virtually free of cost for the municipalities. There is no formula for ensuring equal distribution of investment funds among different geographical areas.

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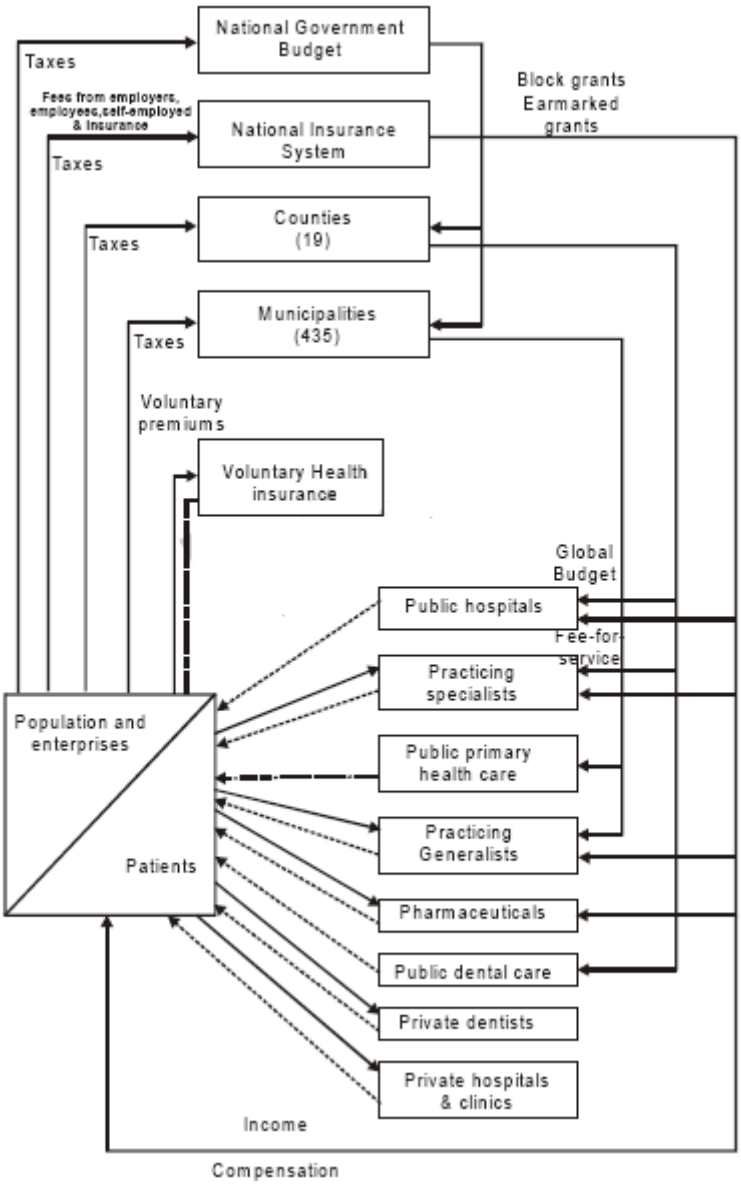

Figure 8: Financial Flow chart

Payment of hospitals

For inpatient stays, hospitals are paid by a combination of cost per case and global budgets. This system has been in use since July 1997. The system of per case funding was originally a payment from the state to the counties. Counties, which traditionally have financed their hospitals by global budgets, are free to change to per case payment for their hospitals or to continue with global budgeting. As of 1999, 18 out of 19 counties had chosen to implement a combination of per case payment and global budgeting on a hospital level. The per case payment is based on the DRG system. Group-specific costs have been calculated based on

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national data, and these costs form the basis for the price system. In 1999, only 50% of the DRG cost was reimbursed.

The present financing system for hospitals replaces a system of global budgeting. Global budgeting was introduced in 1980, originally as a means for controlling costs and securing equal territorial distribution of health services. Countries introduced global budgets in hospital financing as a result of the previous changes in the system of resource allocation from central government to counties themselves. These, in turn, involved a move from retrospective reimbursement of hospital expenditures to counties, to a block grant system, as explained above Financing of hospital services. It was agreed that the block grant system had achieved its aim of better controlling the territorial distribution of health care expenditure. Nevertheless, it encouraged some hospitals to lower performance to reach their budgetary levels. Thus, this commission recommended a reform combining two features: a patient classification system linking cost and output information, and a per-case financing system like the US Medicare system. The aim of the reform was to allow hospitals to admit more patients and have 20% of hospital revenues dependent on the number of patients discharged according to a DRG formula. It was suggested that the new grant be paid by the state as the counties could not carry the financial risk imposed by the DRG system.

As a result of the commission's recommendations, and as part of a centrally designed pilot project, in 1991 two counties switched to a partly case-based financing system for a period of three years, but this system was not universally adopted. Six years later, the pressure to reduce waiting lists led to the general introduction by the central state of the activity-based financing system in the allocation of hospital resources to counties. This change, introduced on 1 July 1997, was mainly motivated by a belief that efficiency would improve. The reform is expected to strengthen the incentives for counties to stimulate hospital activity, which is hoped to contribute to shorter hospital waiting lists and to raise hospitals' productivity. Indeed, the immediate effect of the reform is likely to be a noticeable increase in the number of hospital inpatient treatments. Other important objectives of the reform were to give counties budgetary guidelines, thus providing incentives to carefully evaluate the costs and benefits of each intervention. The new policy also involved stronger central control of hospitals' acquisition of advanced medical equipment.

The implementation of the new system of hospital financing has been as follows. In 1997, a proportion of the grants (70%) continued to be paid by central authorities to counties on a modified needs-based assessment formula. The other part (30%) was paid on the basis of the previous year's inpatient activity, using national standard DRG costs. In 1998, these proportions changed to 55% and 45%, and in 1999, to 50%–50%. The current needs formula is based on a regression analysis of county expenditure on acute hospitals, with different sociodemographic variables, such as age structure of the population, density, travel distances and mortality.

As mentioned above, although counties are not forced to introduce a parallel shift in hospital financing from pure global budgeting to partly activity-based funding, most of them have incorporated such changes. The timing has been as follows. In 1997, 13 out of 19 counties had provisionally adopted the activity related grant system to fund their hospitals, which implied that they simply passed on the received activity-based grants to their hospitals. The remaining six counties continued to finance their hospitals solely through fixed global grants. By 1998,

only two counties upheld global budgeting, in 1999 only one, and from year 2000, all counties are expected to adopt the activity-based financing of their hospitals.

Regarding hospital outpatient activity, traditionally it has been financed partly by a fee for service system and partly via global budgets. Since 1999, day care surgery has been financed based on DRGs. Teaching hospitals receive two additional grants: one to cover teaching and research and the other to finance the treatment of particularly costly patients.

Payment of physicians

As explained in the section on Health care delivery system, outpatient primary and specialized services are delivered in Norway by both public physicians and private practitioners contracted out with the public health care system. Public hospital services, in contrast, are fully provided by public (or quasipublic) employees. Public general practitioners, hospital physicians and other local staff employed by the local governments receive a fixed salary which is centrally negotiated with the Medical Association of Norway. In general, physicians represent a high-income profession in Norway. As regards private (generalist and specialists) physicians and physiotherapists contracted-out with the public system, the funding arrangements are as follows. The municipalities or counties use the funds from the National Insurance Scheme (NIS) as an operational subsidy to pay the health personnel with whom they contract. This operational subsidy is estimated to cover around 35–40% of the physicians' and physiotherapists' income. In return for this guaranteed income, these professionals receive additional per-case payments from the NIS and patient out of pocket fees which are regulated by the state and are lower than market fees. Reimbursements from the NIS are determined through negotiation between central authorities and the Medical Association. The parliament determines all medical charges, and there is an upper limit to the total expenses for one consumer during one year.

Until recently, all physicians and physiotherapists were entitled to receive payment from the NIS, whether or not they had a contract with the authorities. Those who did not have a contract could charge the patients a higher fee to compensate for lack of municipal or county operational subsidies. This system guaranteed all licensed physicians and physiotherapists a secure means of support. However, as these personnel are able to practice wherever they would like (i.e. they can move if they would like a contract), and in order to obtain a more equal distribution of personnel resources in the different parts of the country, this system has recently been subject to reforms which started at the end of the 1990s. Since 1998, NIS funding has been curtailed for physicians and physiotherapists who establish a new practice without a contract with the municipality or county.

However, it is important to clarify that private physicians are not required to enter into a contract with a municipality or county. On the contrary, there are restrictions as to how many physicians and physiotherapists can have a contract in each territorial area. In overstaffed zones, if the municipality is unable to offer more contracts, they may have to forfeit the operational subsidy that they might have received from practicing elsewhere.

Unlike general practitioners in many other countries, general practitioners in Norway in the mid-1990s earned a higher average yearly income than physicians in hospitals. This is partly due to the fact that general practice has become a highly esteemed specialty, and partly due to the fact that general practitioners with a private, contracted-out practice on average obtain

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35% of their income as an annual grant. The remaining income comes from fees for service depending on the amount of work carried out. Of these fees, on average, three quarters is paid directly by the NIS and one quarter is from out-of-pocket fees. There has not been a major income study on general practitioners since 1995. To make it more attractive to work as a hospital-based consultant, the wages for these physicians have been raised 30% on average from 1995–1998. This measure has been successful, and the aim of recruiting more physicians to hospitals has been fulfilled. Today there is greater concern about recruiting general practitioners to some of the rural parts of the country than to the hospitals. The funding arrangements for general practitioners in private practice will change as of 1 January 2001, and the NIS reimbursement of fees for service to general practitioners will become conditional on the general practitioner having signed a contract with the municipality. The aim of this measure is to discourage private practice without a contract, which is most widespread in the prosperous urban areas, in order to free up human medical resources for the remote areas. A similar measure was introduced for private contracted-out specialist physicians two years earlier. From 1998 onwards, private specialists need to have an agreement with the county in order to obtain reimbursement from the public sector. Private physicians with public refunds now form a part of county health plans.

1.7 Germany

Formative features and characteristics of the German health system

There are two separate systems of health insurance: public health insurance and private insurance. Both systems struggle with the increasing cost of medical treatment and the changing demography. About 87.5% of the persons with health insurance are members of the public system, while 12.5% are covered by private insurance.

Statutory (public) health insurance (GKV; Gesetzliche Krankenversicherung)

Germany has the world's oldest universal health care system, with origins dating back to Otto von Bismarck's Social legislation, which included the Health Insurance Bill of 1883, Accident Insurance Bill of 1884, and Old Age and Disability Insurance Bill of 1889. As mandatory health insurance, it originally applied only to low-income workers and certain government employees, but has gradually expanded to cover the great majority of the population. The system is decentralized with physicians in ambulatory practises providing ambulatory care, and independent, mostly non-profit hospitals providing the majority of inpatient care. The statutory health insurance, which insures about 90% of the entire population is -in addition to the pension, unemployment, accident and home care insurance - an essential component of the German social security system and part of the health care system. It is a mandatory insurance for a large proportion of all employees whose income in the last three years was below a given limit. Its character as an employee insurance with compulsory membership for parts of the society is given by the fact that the GKV is financed mainly by contributions of the employees. Only public officers, self-employed people and employees with a gross income above ca. 50000 Euro (€) (adjusted yearly) may join the private system. Task of the GKV is to preserve the health of the insured, to re-establish or improve their health. All insured persons have generally adopted the same entitlement to benefits according to the extent of the 5th Book of Social Law (SGB V) and by § 12 1 SGB V. Benefits must be sufficient, effective and economical and must not exceed what is necessary. Against this background, a health

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insurance company may also provide additional services when based on statutory authorization. This includes services for the prevention of disease (prevention), grants for medical preventive measures, more benefits for home nursing, home care, and supplementary services for rehabilitation. In accordance with the principle of solidarity, membership and premiums to the GKV are - unlike in the private health insurance - not related to age, gender, health status or to a given personal risk for certain disease.

The amount of the insurance contribution depends purely on the economic performance of the insured. The rule is: high income, high contributions - low income, low premiums. The benefits of public health insurance are the same for everyone. Who has a particularly low income, is even in whole or in part exempted from co-payments. Finally, unlike the private, the public health insurance cannot deny anyone membership.

The sickness funds are financed from allocations from the German Health Care Fund (GHCF; Gesundheitsfond). The GHCF is funded by premiums of employees and their corresponding employers. The nationwide premium rates since the enactment of the GHCF on 1 January 2009 amount to date:

• in general: 14.9%

• reduced : 14.3%

To the services provided by the GKV insured persons are involved in most cases by deductibles and co-payments. The co-payment amounts in the supply of drugs, dressings and remedies generally to 10% of the costs with a minimum of 5 €, a maximum of 10 € and not more than the cost of the drug itself. For medicines, the additional payment is 10% of the costs and € 10 per prescription. A planned medical or dental treatment is free for the insured, but a consultation fee of € 10 is payable once per quarter. With measures such as inpatient hospital care and rehabilitation, an insured person contributes 10 € per calendar day to the cost, for a maximum of 28 calendar days. Rehabilitation measures which are conceptually no follow-up rehabilitation, are available through its entire length with additional charge of 10 € per day. Regarding home care, co-payment is 10% of the costs plus a fee of € 10 per prescription.

In summary, in the **public system** the premium

- is set by the Federal Ministry of Health based on a fixed set of covered services as described in the German Social Law, which limits those services to "economically viable, sufficient, necessary and meaningful services"
- is not dependent on an individual's health condition, but a percentage of salaried income
- includes family members - i.e. husband/wife and children are free
- is a "pay as you go" system - there is no saving for an individuals' higher health costs with rising age or existing conditions.

With an aging population, there is an intrinsic risk that, in the long run, the burden to be carried by the young and working generations for the higher share of elderly will run the public system into a huge deficit or result in high premiums.
Capitated care, such as that provided by health maintenance organizations, has been prohibited since the 1930s, but has been recently reconsidered as a cost containment mechanism. Co-payments were introduced in the 1980s in an attempt to prevent over utilization. The average length of hospital stay in Germany has decreased in recent years from

14 days to 9 days, still considerably longer than average stays in the United States (5 to 6 days). Part of the difference is that the chief consideration for hospital reimbursement is the number of hospital days as opposed to procedures or diagnosis. Drug costs have increased substantially, rising for nearly 60% from 1991 to 2005. Despite attempts to contain costs, overall health care expenditures rose to 10.7% of GDP in 2005, comparable to other western European nations, but substantially less than that spent in the U.S. (nearly 16% of GDP).

Private insurance (PKV; Private Krankenversicherung)

In the private system the premium

- is based on an individual agreement between the insurance company and the individual defining the set of covered services and the percentage of coverage
- depends on the amount of services chosen and the individual risk and entrance age into the private system
- is used to build up savings for the rising health costs at higher age (required by law)

The private system is said to be more stable to a changing demography, due to the savings accumulated over time. However with rising life expectancy the premium will also eventually rise for individuals.

There is always discussion about the benefits of the two parallel systems:

- Generally the private system gives its members a good protection at young age, allowing doctors to charge higher fees and offer wider services. Therefore private patients find it typically easier to get a treatment. However with increasing age the private premiums rise, when having children and family there is a premium for each individual and there are only very few ways to go back to the public system.
- The public system is working with budgets for regions and treatment types. That may make doctors, in whose region the budget has been overrun, to postpone treatments to the next budget period, therefore deteriorating patients service. Especially for young working singles the premiums for public insurance are higher than in the private system.
- The treatments covered by the public system are decided by the health ministry, which has so far always resulted in decreasing coverage

Association of (HMO/NHS) doctors (KV; Kassenärztliche Vereinigung)

After their introduction, the GKV quickly gained importance for the professional perspectives of the physicians in general. From the end of the 19th century to the Weimar Republic there were strong arguments between insurance companies and physicians. As a result, practitioners have been able to curtail the influence of the insurance companies and to ensure a monopoly in the ambulatory care of the population.

The monopoly of the KV and the related strict separation between outpatient and inpatient medical care continue to exist as a characteristic and singular element of the German health care system today. Closely related to the overall low level of integration of health care it should be pointed out: the outpatient setting is dominated by small-sized practices. Larger institutions which would be better able to meet complex care tasks - because several medical disciplines and non-medical health professionals are working together in a coordinated manner - yet hardly emerged. The Health Care System of the former German Democratic Republic was at least in its basic structures (clinics, dispensaries) more focused to integrated

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supply concepts. However, after the turn in 1989, the health system of the Federal Republic of Germany extended nearly unchanged on the new countries.

The KVN still have a statutory mandate to ensure the ambulatory medical care of the german population. They are obliged to ensure a qualitatively adequate supply for the nationwide needs. The insurance companies contract directly with the KV and guarantee a fixed amount of allocation. The distribution of the total compensation paid to physicians is t up to the KV. However, a significant restriction of the monopoly position of the KV came with the latest health care reform allowing contracts of the insurance companies with individual physicians or physician groups, even without participation of the KVN.

Outpatient and inpatient care sector

One consequence of the described development is the strict separation between the outpatient and inpatient care sector, which is different to many other countries. Hospital doctors are not allowed to perform out-patient treatments, unless they are specifically authorized by the KV. Therefore, in Germany the treating physician normally changes when a patient is discharged from hospital. The separation of the outpatient and inpatient care sectors not only leads to inefficiencies, but often proves to be accountable for diminished quality of care in case of chronic or more serious diseases. An immediate consequence of the sectoral division is also the pronounced double structure of specialized doctors in Germany. In many other countries, the specialists are working primarily or exclusively in hospitals treatening both inpatients and outpatients. Because of the monopoly of practices to the outpatient treatment, different medical specialty disciplines can be found also in the ambulatory field.

Outpatient care

Ambulatory care includes all health services provided outside of hospitals. By far the largest segment is the care provided by contracted physicians. The outpatient medical care for the health insurance law is ensured by the KV (see above).

The single doctor practice is still the most common form of operation in outpatient medical care. It is expected that new forms of business will spread in the future, allowing for a greater cooperation between the different medical disciplines and utilities. With the introduction of medical care centers (MCC) by the recent health care reform the course has been set in that direction. At the end of 2004, a total of approx. 133,400 physicians participated in the ambulatory care. The main sections were general practitioners and internists.

The German Social Law distinguishes between primary and specialized care. General practitioners, pediatricians and internists are the first point of contact for patients and coordinate medical care on the basis of their knowledge of the entire medical history and on given circumstances of the individual patient. In contrast, specialized doctors take over responsibility in the treatment of a defined disease or organ system. The proportion of general practitioners has declined in recent decades while the percentage of specialists has increased. Meanwhile, greater efforts to promote primary care will be taken. The health insurance companies expect to gain improved quality and efficiency of care from an expansion of primary care and are offering so-called GP models (Hausarzt Modell). Characteristic of these models is the obligation of the insured to consult their family doctor in case of sickness, specialists can be consulted only after referral by the general practitioners.

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As another new form of care, the "structured treatment programs" in ambulatory care were introduced. In the future, a development towards a more integrated form of care can be expected thereby overcoming the separation of the ambulatory, stationary and rehabilitative sectors.

Inpatient care

Inpatient care within the statutory health insurance is divided into two main areas: the area of hospital services and the area of inpatient medical rehabilitation.
In the presence of a serious acute illness making necessary intensified medical care, any patient in Germany can claim for inpatient treatment in an approved hospital. However, it must be proved by the hospital that treatment cannot be guaranteed by outpatient care according to § 39 para I, p. 2 SGB V. The inpatient hospital care is therefore always subordinated to other, usually less costly forms of treatment. The admission for inpatient treatment in an hospital will normally require a referral by a practitioner. Without this referral usually only private patients have access to hospitals. The patient stands in principle free to choose the hospital, however, without a free choice of doctors within the hospital.

After discharge from an hospital, primarily non-medical measures are often needed to restore the performance of such a patient or to avoid a permanent dependence on care. Here, remedies such as physiotherapy, exercise and occupational therapy and other appropriate means are used (§ 107 II 2 SGB V). Such services for medical rehabilitation can be provided only in rehabilitation facilities (§ 111 SGB V) under a doctor's responsibility. The institutional distinction between these two service areas is a German peculiarity, however, this substantive distinction between acute care and medical rehabilitation has recently been repeated theme and subject matter for intensive discussions.

The vast majority of hospitals has 100 to 499 beds. Only 3% of all hospitals have 1,000 beds and more. The hospital care is structured in different levels. Houses with less than 200 beds are usually responsible for basic medical services (surgery, internal medicine, gynecology). Houses with 200 to 500 beds are usually associated with focal care (Schwerpunktversorgung) having additional departments and intensive care facilities. Hospitals with more than 500 beds are generally referred to as the Houses of Maximum Care (Haus der Maximalversorgung). They are equipped for the care of critically ill and severely injured accident victims.

Hospitals are run by different actors. Often, a distinction between public (municipalities, provinces), non-profit (churches, charities) and private organizations is made. Most beds are found in public ownership. However, in recent years the number of public hospitals has decreased significantly: from 1110 in 1991 to 817 in 2002 (-26.4%). During the same period the number of private hospitals increased by 47.5% to 528. This change in the support structures is debated controversely: while one part expects greater cost effectiveness when transferring a public hospital in private ownership, others fear the dominance of economic calculations in medical care at the expense of quality of care.

The German hospitals are a major employer: the annual average in 2002 showed 851,254 fully employed persons. The proportion of the medical staff was around 13%. The above-described reduction of beds in hospitals was not accompagnied by a corresponding reduction in stuff. On the contrary, the number of hospital doctors increased from 1991 to 2002 for 18% to 112,771 in total. Internally, hospitals are generally divided into departments. Most hospitals have

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departments of internal medicine, surgery and obstetrics and gynecology: about 2 / 3 of all patients are treated in these departments. Other departments - such as urology or neurosurgery - are found mainly in large or specialized hospitals. Proper treatment of seriously affected patients is provided by intensive care units, acute first-aid measures are normally given in suitably equipped emergency rooms.

The deployment and management structure of a hospital is divided mainly into the areas of medicine, nursing and administration. The divisions are represented by the medical director, by the nursing management and by the director of administration.

Financial flows in the German health care system

Reimbursement in the outpatient sector

The KV distributes the payments received from the health insurance along a certain distribution key to the doctors. Basis of the doctor's fee for a single performance are the points that are assessed with the medical services in a so-called Uniform Rating Scale (EBM; Einheitlicher Bewertungsmaßstab). The EBM is set at a federal level between the Federal Association of Statutory Health Insurance Physicians (KBV; Kassenärztliche Bundesvereinigung) and the Leading Organization of the Federal Health Insurances (Spitzenverband der Krankenkassen).

In addition, the doctor also generates revenues from separate arrangements. This applies, for example, in the participation in special forms of care such as GP models and structured treatment programs for chronic patients. In addition, physicians will receive fees for the care of private patients, which are reflected in the Scale of Medical Charges and Fees for Doctors (GOÄ; Gebührenordnung für Ärzte). In addition, physicians can earn revenue from individual healthcare services (IGeL; individuelle Gesundheitsleistungen).

With the health care reform in 2004, it has been decided to reorganize the medical compensation. The aim was to compensate adequately the services rendered and, on the other hand, to consider in more detail the morbidity risk, i.e. the risk of increasing expenses due to increased incidence of diseases. The result is a new compensation system which came into effect on 1 January 2009. In essence, this means:

- The reimbursement system characterised by budgets and fluctuating scores has been replaced by an Euro-tariff system. The new system has flat-rate tariff in a manageable number and individual compensations for eligible special services, for example, visits at home. For family doctors and specialists different criteria are applied taking into account differences between primary and specialty care. In the framework of the Euro-tariff, in different German regions reimbursements are adjusted, whereby in particular KV-regions profit in which below-average prices have been paid previously.
- The morbidity risk is transferred to the health insurance companies. This means that for additional services due to intensified treatment additional reimbursement must be provided at the expense of the insurance companies..
- The necessary cost and quantity control is carried out by specific incentives in the Scale of Medical Charges and Fees of Doctors, as well as by quantitative and practice related scales of prices via so-called benefit volumes (RLV; Regelleistungsvolumen).

- Beginning in 2010, financial incentives are set to reduce over-or under-supply that will contribute to a regionally balanced physician density.

Any doctor will receive a standard benefit volume (RLV) depending mainly on the number of treatments in the past. He profits when delivering many, but inexpensive treatments. If he has fewer treatment cases, but expensive equipment, there is less money than before. Moreover, additional services will be rewarded beyond the standard benefit volumes. In summary, this led to a situation that mainly medical specialists in West Germany received honorary decrees for the first quarter, which were up to 50 percent below last year's level. Accordingly, the debate is heated. In some places, patients are treated only on advance payment, doctors close their practices in protest. The protest has the following background:

1. Until now, doctors reported points according to EBM to the KV. The total sum of points was built and, subsequently, the available money paid out. However, the fees varied depending on how good or bad a health insurance company stood financially leading to a remarkable divide, for example between the funds in high-income regions such as Bavaria on the one hand, and such like Mecklenburg-Western Pomerania, with many unemployed and elderly people on the other side. On average, the real value of a point, was 3.8 cents. Since 1 January 2009, it stands at 3.5 cents - no matter what state, no matter what health insurance. With this point value, almost all services are paid equally nationwide. However, more recently, screening procedures, vaccinations and treatment of chronically ill patients are charged extra.
2. The other major innovation is the so-called standard benefit volumes. This means that a certain budget is given to a certain practice. The volume will be communicated to the doctor a month in advance for the following quarter. The sum is composed of the number of patients of the practice in the same quarter last year, of the average value of cases to be treated and of the "weighting factor of age": for retirees, there's more money for the doctor. Overdrawing its budget will lead to diminished compensation for a given service.
3. Patients are almost exclusively settled through DRGs.

Above all, mainly specialized doctors protest - for two reasons: First, it is more difficult with the new packages to redeem expensive technical equipment. For example, X-ray examinations could be individually billed so far. But now they fall into a flat-rate. Specialists with individual practices now fear the competition of hospitals or of practice communities sharing expensive medical devices.

According to the preliminary results of the first quarter of 2009, the Federal Association of Statutory Health Insurance Physicians make up a first balance: fact is that there are winners and losers among doctors. Winners are cardiologists (+ 82%), neurologists (+ 80%) and urologists (+77%) with a plus in income. By contrast, 35% of all doctors have all suffered losses, especially orthopedists, anesthesiologists and otolaryngologists. The intended approximation of reimbursement, especially between East and West Germany, must be considered as "satisfactory" As an example, the report cites the family doctors who stand on an average for a plus of 10 %. 95% of GP's in Saxony-Anhalt profit from the reform but only 14% of their counterparts in Baden-Wuerttemberg. Also in Bavaria, North Rhine Westfalia and Rhineland-Palatinate the plus is far below average growth. Leading among the winners are doctors in

Berlin with 32.2%, followed by Lower Saxony with a gain of 17.6 and Mecklenburg-Western Pomerania, with 15.6% more.

Reimbursement in the inpatient sector

Since 2004, settlement according to DRG (Diagnosis Related Groups: Diagnosis-related groups) is mandatory in German hospitals. DRGs describe a socio-medical classification system with which patients are classified in related groups building the basis for the economic burden required for treatment. In a DRG system, patients are classified on the basis of medical (diagnosis, any treatment) and demographic data (age, sex, weight, and the inclusion of children who are younger than 1 year) in case groups. The case groups, however, serve for medical distinction. Differentiation is made taking into account the economic burden of a given treatment.

Relevant criteria for assigning a patient to a diagnosis-related-treatment group are

- the main diagnosis (often the underlying disease),
- procedures performed in hospital (surgeries, costly tests)
- secondary diagnoses and complications which affect significantly the treatment process
- the artificial ventilation time and
- patient-related factors such as age, sex of the patient or the birth or admission weight in infants.

The international development of DRGs is now almost 30 years old. DRGs were initially developed as a business management tool. This was followed by use as a compensation system in the Medicare section of the U.S.. Meanwhile, the instruments are applied in more than 20 countries with very different health systems. G-DRG (German-DRG) is the name for the German adaptation of the Australian DRG system (AR-DRG). According to § 17 b KHG the German Hospital Federation (DKG), the Leading associations of health insurance and the Association of private health insurance (PKV) are responsible for the introduction of a flat-rate pay system.

German Health Care Fund (GHCF)

The GHCF is a component of the health care reform in 2007, agreed upon by the parties of the grand coalition under the name "Law to strengthen competition in the statutory health insurance. The reform process was accompanied by intensive discussions between the government parties, lasting at least for more than one and a half year. The health care reform in 2007 includes the following main areas:

1. Improving medical care: inter alia opening of the hospitals for outpatient treatment of people suffering from serious or rare diseases; vaccinations and treatments are compulsory statutory health insurance services; requirement for a second opinion when prescribing special, highly innovative drugs; legal claim for home care; legal claim for rehabilitation at the expense of the GKV;
2. Modernizing the statutory and private funds: introduction of choice tariffs, for example GP Tariff) or retention; increased competition among insurance companies; options of merging between insurance companies
3. Reform of Financial Regulation: the GHCF

In the center of the planned reforms of the GKV-financing system is the establishment of a GHCF, which will bundle the financial flows of the GKV (see Figure 1).

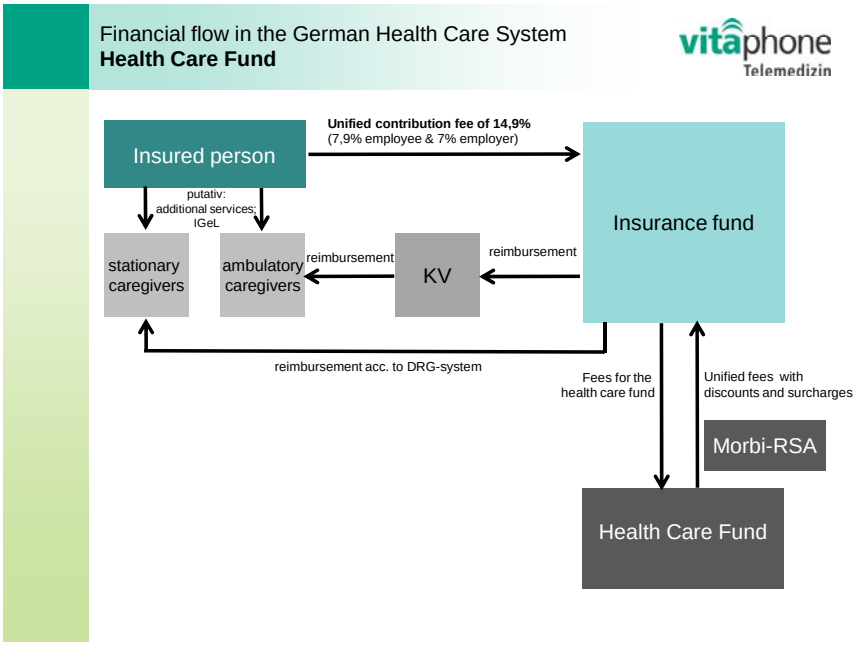

Fig. 1: Schematic drawing of the German Health Care Fund (GHCF)

This means that the financial resources of the statutory health insurance (premium income of insurers and of tax-federal funds) flow into the GHCF and the sickness funds receive -according to certain rules - their financial resources out of this fund.

The GHCF is covering at the start time 100 percent of statutory health insurance spendings. If the insurance companies cannot cover the cost of health care the funding rate can decrease to 95 percent. Up to five percent of the statutory health spending must then be covered through an additional contribution. The financing of private health insurance remains unaffected by the establishment of the GHCF. GKV and PKV remain two financially strictly separated systems.

The GHCF is fed by premium income, which will be borne by the insured and employers, and by tax funded from a federal grant. The health insurance contributions will follow the rules already in force before the 1.1.2009, paid by insured persons and employers. 0.9 percentage points must be borne exclusively by the insured. The remainder of the premium volume is shared equally by em. This grant is expected to rise significantly in coming years.

The contributions are collected by the sickness funds and forwarded to the GHCF. At the same time the mechanism for determining the rate of contribution changes: To date, each insurance company could set their own contribution, while with the GHCF a state-uniform contribution rate (14.9% since 1.7.2009) has been introduced for all health insurances, as determined by the federal government. At this point, the decision-making authority thus moves from the insurance company to the Federal Government.
The health insurance companies will receive - after they have forwarded the premiums to the GHCF - a fixed amount per insured from the GHCF, and, in addition, a risk premium, relevant

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for the amount of sex and age of the insured and certain disease characteristics. In this way, there is a financial redistribution between the health insurance: additional funds from the GHCF are obtained for insured who are older or suffer from certain diseases. This redistribution process is called "risk adjustment" (RSA; Risikostrukturausgleich).

Additional Contribution (Zusatzbeitrag)

Health insurance companies can charge an additional contribution, if allocations from the GHCF are not sufficient. When they are acting economically, they can –on the other hand - pay a premium to its policyholders surplus. The individual additional contribution will become a key differentiator of the statutory health insurance. Whenever there is a gap between expenditure and income from the GHCF, insured must pay a surcharge. For children and dependent partners, there is no additional contributions. For welfare recipients the basic subsistence or welfare office will take over the additional contribution. At the start of the GHCF on 1 January 2009 no federal insurance has raised an additional contribution. Insurance companies with low contribution rates used to emphasize the statement that they will continue to offer their customers a price advantage. It is clear that there is a limit on the additional contribution: nobody must pay more than one percent of his income ("hardship provision"). Additional contributions up to eight euros will be collected without income test. Once a health insurance company levies a surcharge, or increase it, insured have a special right of termination.Health experts suspect that in the first months after the inception, all insurance companies will avoid negative headlines, and hence, the collection of additional contributions. This condition will not hold permanently: from the very moment when the first competitor has ventured out of cover, the bulk of the funds will join.

Increased competition among health insurance

The legislature intends with the introduction of the additional contribution to intensify the competition, which was previously held primarily on the different contributions of the different insurance companies. With the establishment of a nationwide identical contribution rate the additional contribution will be **the** central parameter in the health insurance competition. An increase in competition is expected because the absolute amount of the additional contribution is a clear price signal for the insured.

The federal government expects that competition will prevail in those insurances which act highly efficient, i.e. which provide an efficient and high quality care for their policyholders. A higher efficiency is to allow these funds to dispense with an additional contribution, and distribute instead premiums to their policyholders. Inefficiently working health insurance should, however, raise an additional contribution to help meet their financial needs. In this context a problem must be pointed out: The Federal government hopes that the incentive mechanisms outlined above, will lead to an intensification of competition resulting in better medical care. However, it is highly questionable and debatable whether in fact the quality and price competition is standing in the foreground. The health service will continue to do everything possible to avoid the imposition of an additional contribution, because such a move would lead to a loss of members and reputation for themselves. Therefore, the removal of specific services will be preferred to the introduction or raising of the additional contribution.

Bankcruptcy and mergers of insurance companies

According to a bankruptcy law adopted in 2008, all statutory health insurance can go bankrupt from 1 January 2010. The bankruptcy law is a "central prerequisite" for the introduction of the

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GHCF in early 2009 covering the 16 regional health funds and other insurance companies under federal state supervision. So far, only insurances under federal government - like Barmer or DAK – were able of bankcruptcy. This financial disadvantage ends with the start of the GHCF and the new highly competitive environment. The act provides numerous safeguards against bankcruptcy. The closure or insolvency of a health insurance were only the last resort. If there is no other way for a distressed insurance company, then the affected insured persons, doctors and hospitals should not suffer this disadvantage. The inventor of the GHCF, economist Wolfram Richter, expected in 2009 the first failures of statutory health insurance. The candidates were insurances, which had not adjusted to the increased competition due to the GHCF. The fund will exert enormous pressure. In addition, there will be a series of mergers between health insurers. It is predictable that through such mergers and bankruptcies the number of today around 215 statutory health insurance will drop drastically. Under the conditions of the GHCF and of the various reforms it becomes more difficult for smaller health insurances to hold the necessary financial liquidity. The size of an insurance company become a determining factor in a market that is heavily determined by competition.

Selective contracts, family physician oriented and integrated health care delivery will need the appropriate know-how that can easily be delivered by the larger insurers. Finally, there is the argument of market power over medical providers or pharmaceutical companies. Thus, large insurers can certainly negotiate better discounts for individual substances or complete kits with drug manufacturers as a smaller - and thus save on their drug spending.

In the last 12 months, nearly 30 health insurance companies were swallowed by larger companies, and there's no end in sight. According to media reports, former Health Minister Ulla Schmidt suggests more than 50 public health insurance as unnecessary. Although this was probably meant more in jest, the trend is in sight, because in 1992 there were more than 1200 legal funds, in the beginning of 2009 only around 200. Believing the forecasts, the number of health insurances will decrease within three or four years to below 100. Of these, mainly so called “Betriebskrankenkassen” are concerned, as they have a predominantly healthy clientele with corresponding low contribution rates. This competitive advantage was lost by the health care reform and the associated unit rate.

In many cases, consumers benefit from mergers, because they often save the additional contribution that would be raised without the merger. An additional advantage is the increased market power of merged funds. The larger the fund, the easier they can prevail in contract negotiations with hospitals, doctors and pharmaceutical companies to lower prices and better service. This benefits the patient. However, mergers have not only advantages for the insured because they stimulate mergers also on the opposite parties. Hospital have formed chains and networks of physicians. These are aimed at affecting their bargaining position. Thus, new but expensive treatments get their chances. However, fewer and fewer independent clinics and physicians are left. Patients will often no longer have the choice between physicians and clinics, and must subscribe to co-operation contracts between funds and physicians. On the one hand this might just save the consultation fee. On the other hand it also has its dangers: if insurance companies share incentives to doctors to prescribe only certain drugs for which they in turn have negotiated discounts with pharmaceutical companies, the patient may remain the best drug withheld.

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Morbidity-related-risk adjustment (Morbi-RSA; Morbiditätsorientierter Risikostrukturausgleich)

Due to the morbidity-related-risk adjustment that takes into account the criteria age and gender, differences in structure between the insured of individual insurance companies are set off. With the GHCF, this mechanism has been further developed. What is new is that with introduction of the GHCF specific disease characteristics are taken into account, so the RSA is now known as "Morbidity-related-risk adjustment " (Morbi-RSA). Sickness funds with insured people suffering from chronic and therefore treatment-intensive diseases, get more money from the GHCF.

To this end, the Bundesversicherungsamt has decided on the catalog including now 80 diseases relevant for the morbidity-related-risk (see the list of the diseases of the Federal Insurance Office: including HIV / AIDS, diabetes, COPD, asthma, heart failure, etc.). In these diseases, the average expenditure per insured is at least 50 percent higher than the average expenditure per capita for all insured. These diseases are said to be particularly severe, chronic and require very high expenses. Health insurances with a higher proportion of chronically ill and more expensive insured get a correspondingly higher amount from the GHCF. Critics have long called for such a reform. In particular, representatives of the General Local Sickness Funds (AOK) and some Ersatzkassen designated the former RSA as totally inadequate. In these funds, many people are insured which a private company would never take in: members with a low-income and a comparable high risk of chronic disease.

Risk calculation and assessment of fees according to the Morbidity-related-risk adjustment

The resources of the GHCF must be distributed to the health insurance companies in such a way that they arrive where they are mostly needed for the supply of the insured. First of all health insurance receives for each insured person a basic allowance in the amount of average per capita expenditure in the GKV. For a health insurance company with many old and sick insured, this amount is not sufficient when compared to a company with many young and healthy policyholders. Therefore, this basic package is adjusted by a system of surcharges and discounts (see figure below). For chronically ill patients the insurers get additional surcharges. For the 80 selected diseases morbidity surcharges are obtainable, reflecting the increased spending caused on average by this disease.

The figure illustrates an example of this relationship for five people. For all five persons insurance companies will get the basic package. For an 25-year-old women, there is an age-and sex discount, in case of different additional diseases there are surcharges. Comparable situations apply to the 62-year-old man, with and without diseases.

In addition to surcharges for 80 different diseases, further surcharges are foreseen, i.e. in cases were the insured person receives a disability pension. In these cases, the insured must suffer from a serious medically confirmed condition with additional burden on the health insurance.

Thus, the new risk structure consists of three pillars:

- the surcharges and discounts for age and sex,
- the surcharges in cases of disability and
- the surcharges for different clearly defined diseases

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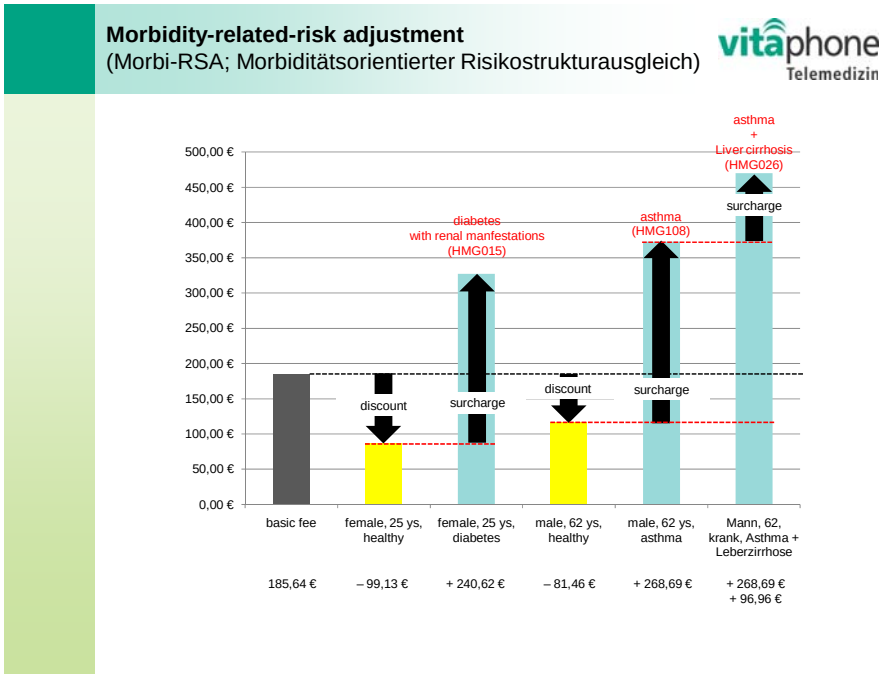

Fig. 2: Schematic drawing demonstrating surcharges and discounts due to the morbidity-related risk adjustment (Morbi-RSA)

Classification of risk groups: For classification by age and sex, the Federal Insurance has formed 40 groups (AGG), for disability pensioners 6 groups (EMG) and for classification into disease morbidity group a total of 106 hierarchical groups (HMG). Overall, the new account focuses on 152-risk groups. Every insured person is assigned to an age-sex group. Thus the basic fee for each insured person is adjusted by age and sex. For probably about one third of the GKV-insured, the insurance will receive additional charges from the disability groups and / or the hierarchical morbidity groups.

Hierarchical morbidity groups: As noted above, for 80 selected diseases a total of 106 morbidity groups were defined by the Bundesversicherungsamt. The number is not identical, because the surcharges are differentiated by the severity of some diseases. On the other hand, there are also cases in which two different diseases with similar care needs are classified in a joint morbidity group. If an insured person is assigned due to its diagnoses to several morbidity groups of the same hierarchy, it is granted only for the highest standing in the hierarchy of morbidity group. For example, within the hierarchy "diabetes", diabetes without complications (HMG019) has the lowest but with renal involvement (HMG 015)) the highest surcharge. In total there are 25 such disease hierarchies. With the hierarchies, the most serious manifestation of each disease will be identified. Only for this, a surcharge is to be granted. Otherwise, differences in medical coding practices or of medical treatment courses could lead to non proper combinations of surcharges.

What will determine whether a health insurance company receives surcharge for an insured morbidity?

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Starting point here are the medical diagnoses. Outpatient doctors and hospitals need to encrypt their accounts with the health insurance according to a predetermined classification system, known as ICD-10. Out of around 15,000 ICD-10 codes approx 3800 are linked with one of the 80 selected diseases and can therefore be assigned a morbidity group. The hospital diagnoses are of a special quality. In the hospitals coding is mandatory. In addition, diagnoses in hospital bills are part of the DRG-system and are controlled by the health insurance under the special payroll checks. Against this background, any relevant inpatient diagnosis leads to an assignment of the insured to a morbidity group and thus to a surcharge. Regarding diagnoses of general practitioners with assignement of the insured person to a morbidity group is valid only when a diagnosis was confirmed by a "second opinion" at least in one billing quarter. For some diseases an additional proof of therapy is needed, especially in cases where a hospital stay (eg, in acute myocardial infarction) or an expensive drug therapy (eg, diabetes mellitus type 1) is medically required.

Determination of the amount of surcharges

When it is known which morbidity groups exist and when an insured person is placed in these groups the amount of surcharges remains to be determined.The basic idea is that the surcharge will not cover the ongoing medical costs, but the additional costs associated with these diseases. For each morbidity group it is therefore tested, which average expenditure is caused by the insured with the appropriate diagnosis in the year after diagnosis. This is called a "prospective model". If for example appendicitis would be among the selected diseases, the surcharge would probably be at 0 Euro, because appendicitis is healed completely and does not produce further costs in the following year in most cases. The situation is completely different from serious and chronic diseases which have been selected. But again: The surcharge, e.g. for an acute myocardial infarction does not depend on the running costs of necessary hospital care, but on the costs generated by this disease in the upcoming needs for care.

Control problems of the morbidity risk adjustment

A morbidity risk adjustment is essential if disincentive effects of GHCF competition should be reduced, but on the other hand an extension for morbidity criteria is associated with various problems. Reference is made in the discussion that the health insurance companies could have an interest not only in having sick insured in their ranks, but also leave them appear sicker than they actually are, just to get higher allocation from the fund. When simultaneously the reimbursement of doctors is also carried by morbidity criteria, there would be some parallel interests with health insurance companies and doctors in an "up-coding" of patients. Presumably, then, new controls are needed to counteract these disincentives.

Moreover, a contradiction exists between morbidity orientation (in financing) and prevention interest. A health insurance plan, receiving for sick insured a higher allocation of funds, is apparently loosing a financial interest to engage in disease prevention and health promotion of their insured, just because it gets more resources for sick insured. However, this problem arises not only from the expansion of the risk for morbidity, but is linked already with the basic structure of the fund competition. In a competitive environment an insurer can never be sure whether the person who today enjoys a relevant measure, will stay with the company in the future. Would he change his health insurance, today's investment in disease prevention and health promotion would in general benefit the competitor.

These examples show a fundamental problem with the use of competitive mechanisms in health care: Health care processes can not be controlled accurately by using economic incentives. Dysregulations will therefore continue to a considerable amount even after the introduction of a Morbi-RSA.

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2.- Options for the implementation of innovative care concepts.

2.1 United Kingdom.

Prevention package for older people

The prevention package raises the focus on prevention as a means of ensuring good health, well-being and independence in later life, by promoting and encouraging uptake of comprehensive health and social care services for older people. Announced in 2008, the health prevention package was launched on 22 July 2009.

As health and well-being are major concerns for people in later years the health prevention package forms the Department of Health's main contribution to the government's ageing strategy Building a Society for All Ages which was launched on 13 July 2009 by Phil Hope, Minister of State for Care Services and Angela Eagle, Minister of State for Pensions and an Ageing Society.

The prevention package:

- brings together information on existing health 'entitlements' including sight tests, flu vaccination and cancer screening;
- promotes best practice around falls prevention and effective fracture management;
- introduces measures to improve access to affordable footcare services;
- updates national intermediate care guidance;
- summarizes existing progress on audiology and telecare.

The Department of Health has launched a pilot programme to test and evaluate a range of models of integrated care. The programme of Integrated Care Pilots is designed to explore different ways in which health and social care could be provided to help drive improvements in local health and well-being. ICP allows communities to take a fresh look at how to deliver such care, based solely around the needs of the local population. The aim is to look beyond traditional boundaries (e.g. between primary and secondary care) to explore new, integrated models.

Integration refers to partnerships, systems and models as well as organisations - crossing boundaries across primary, community, secondary and social care.(Department of Health, United Kingdom, 2010)

Integrated care Pilots

When it was announced as part of the Next Stage Review, the integrated care pilot programme generated considerable interest across the health and care community - with a total of 108 pilot applications received by the November 2008 deadline.

The applications received provide a good geographical spread, with proposals from all 10 SHA regions. They also cover a wide range of health categories, including long term care, urgent care, care of the elderly, mental health and diabetes and involve partnerships between primary care, social care, secondary care, the voluntary and private sectors.

Following a rigorous two-stage process, final 16 sites chosen for the programme of integrated care pilots, and were announced on 1 April.

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The 2nd of July 2009, the 16 Integrated Care Pilots (ICP), announced by the Department of Health began their innovations in the integration of service provision. This is part of a two-year programme, transforming the way people experience health and social care.

The pilots will run for two years and will be evaluated over three years against a set of national and local measures. Six sites have been selected for deeper evaluation by independent external evaluators.

The pilots vary from developing new models of long-term condition management to help patients choose their end of life care, to enabling people to self-manage COPD care. Pilot sites are working across primary, secondary, community and social care services, public and third sector organisations to forge new partnerships, systems and care pathways.(Department of Health, United Kingdom, 2010)

NHS Act 2006 partnership arrangements

The framework provided by the National Health Service Act 2006 means money can be pooled between health bodies and health-related local authority services, functions can be delegated and resources and management structures can be integrated.

The arrangements allow commissioning for existing or new services, as well as the development of provider arrangements, to be joined-up. They were previously referred to as Section 31 Health Act flexibilities, and cover:

- lead commissioning
- integrated provision
- pooled budgets.

In England, Section 31 of the Health Act 1999 has been replaced by Section 75 of the National Health Service Act 2006, which has consolidated NHS legislation. The new provision is in exactly the same terms, and existing Section 31 arrangements will continue as if made under the new powers.

Any new partnership arrangements should refer to the new powers under Section 75, rather than to Section 31. Similarly, previous grant arrangements known as Section 28 A and Section 28 BB have changed as result of the NHS Act 2006, and are now known as Section 256 and 76 respectively.(Department of Health, United Kingdom, 2010)

Integrated Care Network

The Integrated Care Network was established in October 2003 and formed part of the Care Services Improvement Partnership (CSIP) in April 2005.

The Integrated Care Network (ICN) provides information and support to frontline NHS local government organization as seeking to improve the quality of provisions to service users, patients and careers by integrating the planning and delivery of services. Key to the role of the ICN is facilitating communication between frontline organizations and government, so that policy and practice inform each other effectively.

In April 2005, the Department of Health commissioned the ICN to maintain the S31 budget notification database. It is now the main point of contact for the Department of Health for work around Health Act Flexibilities, Section 31 and Care Trust development.

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The work of the ICN seeks to impact on the five pillars that underpin our purpose:

- Access to care
- Reshaping care services
- Greater engagement with local communities and those experiencing social inclusion
- Reshaping of financial and other resource flows
- Developing and redesigning workforce patterns.

The aim of ICN is to promote the wider objectives of integration within policy for service improvement.(National Health Service, United Kingdom, 2010)

Care Trust

Care trusts were introduced in 2002 to provide better-integrated health and social care. Care Trusts are a new type of organization within the NHS, and bring together various health services and delegated local authority services. They provide a way to integrate and co-ordinate health and social care services to provide improved customer focused services that meet the needs of local communities.

Care trusts are set up when it is clear they will result in clear service improvements for users - not to resolve structural and operational issues. By combining both NHS and local authority health responsibilities, care trusts can increase continuity of care and simplify administration.

Care trusts create a single, direct link between local government and the commissioning of high quality health and local government services. This means that local government can exercise its community leadership role more effectively in improving the health outcomes of the community. It also closer links between the NHS and the broader range of local authority services and responsibilities that support the health service.(Department of Health, United Kingdom, 2010)

Delayed Discharges

The Government is committed to reducing the number of patients who are delayed in hospital despite being fit to be discharged. As part of this strategy, if a patient is delayed from discharging from acute services solely because supporting community care arrangements are lacking, the local authority at fault will have to financially reimburse the relevant NHS acute trust. In return, trusts must notify social services departments of patients who may require community care.
The delayed discharge grant has now been incorporated into local authority baselines.(Department of Health, United Kingdom, 2010)

Long term conditions model

The NHS and Social Care long term conditions model draws on local and international expertise to improve the health and quality of life for those with long term conditions. This model:

- Provides personalized and systematic support, based on what works best for people in NHS and social care systems
- Provides a structured and consistent approach to help local health and social care partners deliver integrated care
- Helps ensure effective joint working between all those involved in delivering care, including secondary care, ambulance trusts, social care and voluntary and community

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organizations. Patients need to experience a seamless journey through the health and social care systems.

The Department of Health recommend to:

- Use multi-professional teams and integrated patient pathways to ensure closer integration between health and social care.
- Match care with need, using different interventions for patients with different degrees of need.

There are three levels of need and care:

Level 1: Supported self care: Helps individuals and their carers develop the knowledge, skills and confidence to care for themselves and their condition effectively.

In January 2008 the Prime Minister made a commitment to a patients' prospectus setting out how the 15.4 million people with long term conditions can access a choice of self care services.

Your health, your way – a guide to long term conditions and self care was launched on the NHS Choices website in November 2008. It sets out the support that patients with long term conditions could expect from April 2009:

- local services provided by primary care trusts (PCTs) and local authorities
- locally specific information through NHS Choices and other formats
- choice to support self care.

This is not new policy but draws together existing work and information. It covers healthy lifestyle choices and the four pillars of support for self care:

- information
- tools
- skills
- supportnetworks

Level 2: Disease-specific care management: Provides people who have a complex single need or multiple conditions with responsive, specialist services using multi-disciplinary teams and disease-specific protocols and pathways. These include the national service frameworks (NSF) and quality and outcomes framework (QOF).

In this framework was developed the Disease Management Toolkit, that is a good practice tool for the NHS. This free, web-based tool provides data at primary care trust (PCT) level on conditions contributing to secondary care emergency bed days.

The toolkit will help decision-makers, commissioners and deliverers of care for people with long term conditions understand the conditions that are having the greatest impact in their area. DMIT can help you analyze the likely impact of a range of possible commissioning options. This can help you decide which services to commission locally.

Level 3: Case management: Requires the identification of high intensity users of unplanned secondary care. Case management is a service led by a community matron or case manager that provides proactive, coordinated care to people who have a complex mix of health and social care needs. It provides an intense level of care, preventing people from unnecessary

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admission to hospital and providing care in the person's home or community setting. It relieves carers of having to coordinate services and navigate a range of health and social care systems.

Case management was introduced to improve care for vulnerable people who often experience gaps in services, and to reduce demand on secondary care services. It has been driven by the public service agreement (PSA) target to reduce emergency bed days through improved care.(Department of Health, United Kingdom, 2010)

How is it being implemented?

Primary care trusts (PCTs) and other commissioners of health and social care services need to identify the most vulnerable patients with complex, single or multiple long term condition needs. Patients that are most at risk of unplanned hospital admission (referred to as very high intensity users) should be offered the case management service.

A whole system approach is required. Community matrons and case managers must integrate with other parts of the health and social care system, working alongside GPs and others in the primary health care team - as well as the local acute trust, mental health care providers and social services. It calls for a multidisciplinary team approach. Teams need to have the appropriate mix of skills to meet the needs of high intensity users and people who require coordinated and seamless care.

Personalized case management for patients with multiple or single complex conditions can improve their quality of life, reduce emergency hospital admissions or help them return home more quickly if they are admitted. PCTs are encouraged to undertake local monitoring and evaluation of case management. Many are seeing improvements in care and reductions in emergency bed days.

Patients at risk of re-hospitalisation

Case finding tools

To help PCTs identify patients at high risk of future readmission to hospital, the Department of Health offers specialized software, the patients at risk of re-hospitalization (PARR) case finding tool. It was developed by the King's Fund, Health Dialog UK and New York University and became nationally available from September 2005.

The latest version, PARR++ (November 2007), is more accurate, more user-friendly, brings more flexibility in how data is displayed and generates a wider range of reports.

PARR++ is free to download from the King's Fund website and is available on CD-Rom by emailing the long term conditions team.

The combined predictive risk model

A second tool to predict patients at high risk of admission is a calculation method, known as the combined model. Developed by the King's Fund and partners on behalf of DH, it is a method of identifying people who have never had an admission, but who are predicted to be future high users of secondary care services.

Relevant interventions can be provided at a much earlier stage, improving care and preventing or slowing down deterioration. This method of prediction has huge potential to support better commissioning.

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The combined model uses a more powerful combination of hospital and community data to increase predictive power. The model is based on the poplulation of Croydon, where it was piloted, and may need altering for other PCTs to implement. This requires programming and analytic skills. In addition, it needs central data sharing to be effective.

Risk prediction network forum

In January 2008, was set up a risk prediction network on NHS Networks. The network provides a nationwide forum to engage health and social care groups, including commissioners, clinicians, community matrons, NHS and social care managers. The forum is a place to share ideas, experiences and knowledge on different methods of predicting and stratifying risk of local health populations.(Department of Health, United Kingdom, 2010)

Whole System Demonstrators

The Whole System Demonstrators are exploring the exciting possibilities opened up by truly integrated health and social care working supported by advanced assistive technologies such as telehealth and telecare.

The demonstrators will lead to a better understanding of the level of benefit associated with such developments. They will also help fast track future change by addressing the key implementation barriers and providing solutions for the wider NHS and social care(Department of Health, United Kingdom, 2010).

Health Services management centre. University of Birmingham

As part of its long-term conditions programme, HSMC has supported the NHS/Kaiser Permanente development programme, a key element of which is to enable NHS organisations to adapt lessons from Kaiser Permanente's approach to the management of people with chronic diseases.

The programme has included study visits to Kaiser by clinicians and managers, and work with three NHS Beacon sites to support the adaptation of Kaiser's approach. This has included support to the Beacon sites from Kaiser's staff, including work on self care and medical leadership.

HSMC is establishing a collaborating centre with Kaiser Permanente with the aim of:

- Providing a focus for NHS organizations wanting information about Kaiser
- Providing a resource for NHS organizations to network with each other in adapting Kaiser's principles
- Providing a focal point for Kaiser in understanding NHS developments
- Facilitating study tours to Kaiser for NHS clinicians and managers
- Developing proposals for further research and comparisons between the NHS and Kaiser
- Networking with organizations in other countries that are adapting Kaiser's principles(University of Birmingham, Health Service Management Centre, 2010).

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The Oxford Health Alliance

The **Oxford Health Alliance** is about preventing and reducing the global impact of chronic disease. It stands for innovative action with diverse stakeholders around three risk factors – tobacco use, physical inactivity and poor diet.

The Oxford Health Alliance is concentrating its efforts on six priority areas.

1.- **The economic argument for prevention:** The costs of chronic disease are already vast, and without urgent action these costs will continue to increase.
2.- **Prevention in the workplace:** Chronic disease risk reduction in the workplace can have a major impact on the health of employees and their families, while also demonstrating social responsibility and improving productivity.
3.- **Youth, children and future health:** The insights and enthusiasm of young people can change perceptions and lifestyles of future generations.

4.- **Environmental design for prevention:** Architects, urban planners and transport engineers (among many others) can create environments in which healthy choices are easy choices.

5.- **Industry's role in prevention:** Prevention efforts by companies and industries can have a far-reaching effect on consumers and communities.

6.-**Law and health:** Exploring the relatively untapped potential for the law and health policy to interact to modify chronic diseases determinants that are generated in the way we live.(Oxford Health Alliance, 2010)

National Institute for Health Research

The goal of the National Institute for Health Research (NIHR) is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public. The NHS reputation for international excellence is growing as it gains recognition for being the preferred host for collaborative and multi-centred research in the public interest in partnership with and for industry. This will benefit patients, society, the NHS and all our stakeholders.

The NIHR will work with key partners involved in the different elements of NHS research.

The NIHR is directed by Professor Dame Sally C. Davies, Director General of Research and Development at the Department of Health.

An **Advisory Board** provides strategic advice on the direction, implementation and management of the NIHR.

The Institute manages its activities through four main work strands:

- **NIHR Faculty**: supporting the individuals carrying out and participating in research
- **NIHR Research**: commissioning and funding research
- **NIHR Infrastructure**: providing the facilities for a thriving research environment
- **NIHR Systems**: creating unified, streamlined and simple knowledge management systems

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An schema of the National Institute for Health Research is shown in figure 9.

Figure 9. Structure of the National Institute for Health Research.

The annual budget for the NIHR incorporates all previously existing funds for NHS research in England. The budget also incorporates NHS funding that supports clinical research and academics.(National Institute for Health Research, United Kindgdom, 2010)

2.2 Spain.

The Spanish National Health System offers a common portfolio of services in all the Spanish territory. This portfolio must be offered in all Spain so as the different autonomies (self-governed regions) in Spain can approve their own portfolio of services, these have to include, at least, the same services included in the common portfolio of services.

The common portfolio of services in promotion of health and prevention of illness and deficiencies include:

1.- Interdisciplinary and transverse programs of health promotion and education to improve life styles.

2.- Interdisciplinary programs of protection against health risks and prevention of illness, deficiencies and injuries.

3.- Transverse programs of protection against health risk, prevention of illness, deficiencies and injuries, and of education and promotion of health, during the different stages of life with the purpose of prevent transmissible and non-transmissible illness, injuries and accidents.

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4.- Programs of health prevention and promotion to different groups of society with special needs and, also, to eliminate or reduce inequalities in health.(BOE,)

The Integrated Care in Spain was firstly promoted during the 90´s but it has not been developed in all the National Health System. In some areas, as in Andalucia, there have been many initiatives to incorporate this concept to the health care management programs. For example, **the Clinical unit of integral medical care (UCAMI) in the Hospital Virgen del Rocío[1], Sevilla.** This hospital has a Clinical Unit of Integral Medical Care (UCAMI) that develops a continuity of care programme. To promote the investigation and education of the doctors in this field, the Hospital has signed a three year partnership with the Bridgepoint Health Hospital in Toronto, specialised in prevention and complex chronic illness management. The UCAMI is the leader of the project that will focus in three areas: telemedicine and other tools of e-health as a alternative way of medical care, investigation to improve the attention to the patients and education for specialist doctors by means of exchanges.

Other hospitals in Spain that has a special unit to develop integrated care programs are:

-Hospital Infanta Margarita de Cabra,

-Unit of Continuity Medical Care (UCA). Hospital de Valme,

-Group for Integral and Continuous Medical Care (GAMIC). Cadiz

-Unit for Pluripathology and Integral Medical Care (UPPAMI). Hospital UPPAMI 12 de Octubre. Madrid

- Hospital S. Juan de Dios del Aljarafe

In Spain there is not a common programme to promote disease management programs for chronic patients. Despite of this there have been pilot experiences in different hospitals in order to develop this kind of programs that had been based on the USA´s models or developing new organizational models of medical management.

Some of the organizations that have developed programs for chronic patients are:

Hospital clínic barcelona. The CHRONIC program has been developed by the Clinic Hospital of Barcelona as global management of the chronic patient (of COPD) after discharging from hospital. The main aspects considered in the program are: exhaustive revision of the patient, self-management, educational program, personal plan according to the international guidelines, interaction between the “case” nurse and the primary attention team and a remote contact system with a specialized nurse and primary attention doctor by means of a technology platform with the possibility to realize calls in a website.(OPIMEC Observatorio de Prácticas Innovadoras en el Manejo de Enfermedades Crónicas Complejas, 2010)

Consejería de Murcia. The “Consejeria” (Ministry) of Health of Murcia has submitted a Project Collaboration with the WHO Global Redesign Health Care for Chronic Diseases. This project stems from a joint initiative with the aim of improving the quality of the results obtained in the care of patients with diabetes and COPD. The project is part of the WHO initiative "Innovative

[1] http://www.huvr.es/

Care for Chronic Conditions" (Innovative Care for Chronic Conditions) and has since its inception with the institutional and methodological support of this organization. The project, coordinated by the Program Management EMCA quality of care, involving four hospitals and two primary care managements of the Autonomous Community of Murcia, during the next two years, will analyze the actions and benefits currently offered by health services in relation to chronic diseases, aiming to promote and implement the necessary changes to deliver higher quality care for chronic health problems.(FAECAP Federación de Asociaciones de Enfermermería Comunitaria y Atención Primaria,)

Complejo hospitalario universitario Juan Canalejo. A Coruña[2]. One of the most innovative projects launched by the Hospital Juan Canalejo aims to prevent social exclusion of patients with chronic or long periods of convalescence and continue their education towards their reintegration.

Following a decision by the EU Council to provide access to learning opportunities for all emerges a project called "e-learning opportunities for adult patients during their stay in hospitals", funded by the European Commission under the Socrates program and the participating educational institutions in different countries and coordinated by the Austrian institution Die Berater.

This program involves the Spanish Innovation Group and Educational Technology at the University of Santiago de Compostela (USC) and the area of e-learning Supercomputing Center of Galicia (CESGA).

The program is developed by combining online learning with face workshops and tutorials, having common technology, the course and methodology.(Global University Network for Innovation-GUNI, 2010)

Some "Autonomies" has also increase the portfolio of services in primary care to include specific attention to chronic patients:

Health Service of Castilla- La Mancha. In this region the portfolio of primary care includes the following services:

1.- Chronic Care: Hypertensive
2.- Chronic Care: Diabetes
3.- Chronic Care: COPD
4.- Chronic Care: Stuffed
5.- Chronic Care: Hypercholesterolemia

Finally, the **Agency for Health Technology Evaluation**[3] (AETS) was set up in 1994 as an organ integrated in the Health Institute "Carlos III". Its mission is to attend to all the consultive necessities from the National Health System related with its Health Care Policy, along the prevailing lines of the more advanced Health Systems.

[2] http://www.hospitalcoruna.es/

[3] http://www.isciii.es/htdocs/investigacion/Agencia_quees.jsp

In order to achieve that goal, the AETS offers objective assessments about sanitary, social, ethical, organizational and economical impacts generated by health and medical techniques and procedures. These assessments contribute to support the authority decisions and other agents with scientific basis when deciding about:

1.-Sistematical introduction of new technologies in the clinical practise;

2.-Definition of suitable criterion of use for technologies already established; or

3.-Service health organization.

This general work of support to the decision procedures about sanitary assistance was consolidated and concreted by the Spanish act "Ley 16/2003, de 28 de mayo, de Cohesión y Calidad del Sistema Nacional de Salud", that binds the AETS resolutions to the updating procedure of the portfolio services.(Instituto de Salud Carlos III, 2010)

One of the main **functions** of the AETS is to evaluate health technologies as a technical tool to base the selection, incorporation and diffusion of them in the Spanish Health System. This function is enact by:

R.D. 1415/1994, 25th of June

R.D. (Decree) 1893/1996, 2nd of August

R.D. (Decree) 1555/2004, 25th of June.

R.D. (Decree) 63/1995, 20th of January, about regulation of sanitary portfolio services of the National Health System, that establishes a mandatory evaluation of effectiveness and security as well as the effective contribution that offer the attentions, activities and services of prevention, treatment or recovery of illness.

Ley (Act) 16/2003, de 28 de mayo, de Cohesión y Calidad del Sistema Nacional de Salud, that makes compulsory the evaluation by parlamentarian mandate.

The specific functions of the AETS are defined in the Decree "R.D. 375/2001, de 6 de abril" are the following:

-The evaluation of health technologies as a technical tool to base the selection, incorporation and diffusion of them in the Spanish Health System , in coordination with the "Dirección General de Cohesión del Sistema Nacional de Salud y Alta Inspección" (General Direction for the National Health System Cohesion and High Inspection).

-To identify and inform about new and established technologies that have to be evaluated.

-To establish, supported by scientific basis, the medical, economical, ethical, and social impact, generated by the use of different technologies.

-The production, revision, evaluation and synthesis of the scientific information related with the medical, economical, social and ethical impact, from technologies.

-To contribute to achieve an appropriate education for health professionals to achieve a correct use of the technology.

- To encourage the coordination for the socio-economical evaluation of the medical technologies in Spain.

-To develop international projects in relation with the evaluation of health technologies.(Instituto de Salud Carlos III, 2010)

The AETS is an autonomous organ that can develop its commercial **activities** by its own. So, AETS realize its work with the National Health System at the same time that collaborate with any public or private corporation interested in the evaluation of technology, according to contract agreement the had signed.

Independently of the legal framework why the AETS develop a work, its main activities are:

-To produce public reports about evaluation of health technologies, according to its annual programme that will give priority to those considered as a priority and important technology to the National Health System

-To produce reports requested by public or private companies and institutions.

-To produce short reports for Health Administration Units. These short reports can be of any of the previous categories but with a lower degree of depth and extent. They are usually demanded by Directive Unities of the Health and Consume Ministry or other administrations.

-To detect Emerging Technologies (SINTESIS[4]: new technologies). SINTESIS is an information system about new and emerging health technologies that is developed as a result of a international recognised strategy called "early warning" or "early assessment. This strategy tries to identify the evaluation necessities for innovation in different areas and clinical specialities, detecting the main welfare impacts and give an anticipate answer to the sanitary administrators that will have to face a decision about those innovations.

-Tutelary use of Health Technology as a procedure to evaluate and give essential information to decide about the inclusion of Health Technology in the Portfolio Services of the National Health System.

-Promotion of Evaluative Investigation by means of funds.

-Specific Investigation Projects.

-Teaching and formative programmes

-International collaborations.(Instituto de Salud Carlos III, 2010)

2.3 United States of America

Integrated care

Cherokee Health Systems[5]

Cherokee Health Systems believes in a type of holistic care called Integrated Care. This biopsychosocial approach to health care addresses the whole person by integrating behavioral services into primary care. By combining the best traditions of primary care (adult, family practice, pediatric) and mental health services the integrated health care team is able to treat the whole person - mind and body so all patient needs are met.

[4] To access SINTESIS http://sintesis.isciii.es/
[5] http://www.cherokeehealth.com/index.php?page=About-Us-Integrated-Care

Behavioral health consultants work within a primary care setting and are involved in on site and timely assessment, brief intervention and consultation with patients. Services include education, behavioral management and treatment for mental health disorders. After meeting with a physician or nurse, a psychologist may assess and treat patients with behavioral concerns and work with the medical provider regarding referral questions and follow-up.(Cherokee Health Systems, 2010)

Management programs for chronic patients

The Chronic Care Model. Maccoll Institute For Healthcare Innovation

The Chronic Care Model (CCM) identifies the essential elements of a health care system that encourage high-quality chronic disease care. These elements are the community, the health system, self-management support, delivery system design, decision support and clinical information systems. Evidence-based change concepts under each element, in combination, foster productive interactions between informed patients who take an active part in their care and providers with resources and expertise.

The Model can be applied to a variety of chronic illnesses, health care settings and target populations. The bottom line is healthier patients, more satisfied providers, and cost savings.

Development of the Chronic Care Model

The staff at the MacColl Institute for Healthcare Innovation developed the CCM by drawing on available literature about promising strategies for chronic illness management, and organizing that literature in a new more accessible way. The Model was further refined during a nine-month planning project supported by The Robert Wood Johnson Foundation, and revised based on input from a large panel of national experts. It was then used to collect data and analyze innovative programs recommended by experts. RWJF funded the MacColl Institute to test the Model nationally across varied health care settings, creating the national program, "Improving Chronic Illness Care"[6] (ICIC).

Refinements to the Chronic Care Model

In 2003, ICIC and a small group of experts updated the CCM to reflect advances in the field of chronic care both from the research literature and from the scores of health care systems that implemented the Model in their improvement efforts. They list more specific concepts under each of the six elements. Based on more recent evidence, five new themes were incorporated into the CCM:

- Patient Safety (in Health System);
- Cultural competency (in Delivery System Design);
- Care coordination (in Health System and Clinical Information Systems)
- Community policies (in Community Resources and Policies); and
- Case management (in Delivery System Design).

[6] http://www.improvingchroniccare.org/

The Model element pages have been redesigned to reflect these updates. Each page describes the overall strategy for each element, and the health system change concepts necessary to achieve improvement in that component. The refinements have been emphasized in bold typeface for ready identification.(Improving Chronic Illness Care, 2010)

Kaiser Permanente Model[7]

Kaiser Permanente Health Care Model is organized according to three levels, which depends on the patient gravity. This management model is based on six main principles: integration, active management of patients, clinical leadership, keeping patients out of the hospital, self-management and shared care and information use. The main results of the model are the integrated attention, decrease of hospital stays and avoidable stays, as well as prevention and control of chronic illness.

The main difference with the Chronic Care Model seen in the previous point is that the active management of patients has higher importance depending on the degree of gravity of the patient.

Indiana Chronic disease Management Program

The Indiana Chronic Disease Management Program (ICDMP) was developed through a joint effort between the Indiana Office of Medicaid Policy & Planning and the Indiana State Department of Health and implemented in June 2003. The program deals with Diabetes, Asthma, Congestive Heart Failure Stroke, AIDS and HIV cases.

The goals of the ICDMP:

- Build a sustainable comprehensive, locally based infrastructure
- Strengthen the existing public health infrastructure
- Help improve quality of health care for patients with chronic diseases.

The ICDMP focuses on developing linkages between care management and primary care by providing health care providers with tools to better manage chronic care and patients with self-management tools to be more active participants in their health care.

The program has the following components:

- Call Center for all patients
- Nurse Care Management for high risk patients
- Collaborative Training for primary care practices
- Patient Registry for all patients.

The ICDMP is a statewide program and includes Medicaid recipients in both primary care case management and risk based managed care.(OPIMEC Observatorio de Prácticas Innovadoras en el Manejo de Enfermedades Crónicas Complejas, 2010)

Vermont Medicaid chronic care initiative[8]

[7] https://www.kaiserpermanente.org/

[8] http://www.vtccmp.com/

The State of Vermont offers an initiative to help to understand health conditions to patients and shows how to take better care of yourself.

The Chronic Care Initiative offers a nurse (APS Health Coach) to provide education about overall health and ways to feel better every day. The nurse can helps patients to have a better knowledge about how to talk to doctor about treatments. The nurses work with a team of social workers as well as care coordinators and health educators to assist patients with health needs.

The Vermont Chronic Care Initiative works to improve chronic conditions, to helps patients to take control of their health, to remind patients to take care of their health and to supports patients relationship with their doctor.(APS Health Care, et al., 2010)

The agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ)[9] is the health services research arm of the U.S. Department of Health and Human Services (HHS), complementing the biomedical research mission of its sister agency, the National Institutes of Health. AHRQ is a home to research centres that specialize in major areas of health care research such as quality improvement and patient safety, outcomes and effectiveness of care, clinical practice and technology assessment, and health care organization and delivery systems. It is also a major source of funding and technical assistance for health services research and research training at leading U.S. universities and other institutions, as well as a science partner, working with the public and private sectors to build the knowledge base for what works—and does not work—in health and health care and to translate this knowledge into everyday practice and policymaking.(Agency for Healthcare Research and Quality, 2010)

AHRQ's customers are decisionmakers who need objective, evidence-based, and timely information to make informed decisions about the health care they provide, receive, and purchase. These customers include clinical decisionmakers, health care system decisionmakers, policymakers, and patients.

Clinical Decisionmakers: The evidence uncovered through AHRQ-sponsored research and tools developed from those findings help clinicians, consumers, patients, and health care institutions make informed choices about which treatments work, for whom, when, and at what cost.

Health Care System Decisionmakers: Health plan and health care system managers use the findings and tools developed through AHRQ-sponsored research to make choices on how to improve the health care system's ability to increase access to care and deliver high-quality, high-value care. Purchasers use the products of AHRQ-sponsored research to obtain high-quality health care services.

Policymakers: Public-and private-sector policymakers use the information produced by AHRQ to expand their ability to monitor and evaluate the impact of system changes on outcomes, quality, access, cost, and use of health care and to devise policies designed to improve the performance of the system.

Organizational Structure

[9] http://www.ahrq.gov

AHRQ has nine major components. They are:

- Center for Practice and Technology Assessment: CPTA directs the evidence-based practice program, consisting of: (1) the Evidence-based Practice Centers that develop evidence reports and technology assessments; (2) the Internet-based National Guideline Clearinghouse®; (3) the U.S. Preventive Services Task Force; and (4) intramural and extramural research and evaluation on translating evidence-based findings into clinical practice. CPTA also is responsible for research on the assessment of medical technologies, including conducting and sponsoring technology assessments to assist decisionmaking in other agencies.
- Center for Outcomes and Effectiveness Research: COER conducts and supports studies of the outcomes and effectiveness of diagnostic, therapeutic, and preventive health care services and procedures.
- Center for Primary Care Research: CPCR conducts and supports studies of primary care and clinical, preventive, and public health policies and systems, including the effective application of information technology in health care.
- Center for Organization and Delivery Studies: CODS conducts and manages studies of the structure, financing, organization, behavior, and performance of the health care system and providers within it.
- Center for Cost and Financing Studies: CCFS conducts and supports studies of the cost and financing of health care and develops data sets to support policy and behavioral research and analyses.
- Center for Quality Measurement and Improvement: CQMI conducts and supports research on the measurement and improvement of health care quality, including surveys regarding people's experiences with health care services and systems and research related to patient safety and medical errors.
- Office of Management: OM directs and coordinates Agency-wide administrative activities, including human resources, financial management, information resources management, and other support services.
- Office of Research Review, Education, and Policy: ORREP directs the scientific peer review process for grants and Small Business Innovation Research (SBIR) contracts, assigns projects to Agency components, plans and manages Agency health services research training and career development programs, develops and implements Agency policies and procedures regarding extramural research programs, and evaluates the scientific contribution of proposed and ongoing research, demonstrations, and evaluations.
- Office of Health Care Information: OHCI designs, develops, implements, and manages programs for disseminating the results of Agency activities, including public affairs, print and electronic publishing and dissemination, reference services, research translation and synthesis, and liaison activities with State and local health policy officials.(Agency for Healthcare Research and Quality, 2010)

Technology Assessments

The technology assessment program at the Agency for Healthcare Research and Quality (AHRQ) provides technology assessments for the Centers for Medicare & Medicaid Services (CMS). These technology assessments are used by CMS to inform its national coverage decisions for the Medicare program as well as provide information to Medicare carriers.

AHRQ's technology assessment program uses state-of-the-art methodologies for assessing the clinical utility of medical interventions. Technology assessments are based on a systematic review of the literature, along with appropriate qualitative and quantitative methods of synthesizing data from multiple studies.

Technology assessments may be done in-house by AHRQ staff, or they may be done in collaboration with one of the Evidence-based Practice Centers. When available, technology assessment topics are linked to corresponding information on the CMS Web site.(Agency for Healthcare Research and Quality, 2010)

National Advisory Council for Healthcare Policy, Research and evaluation

The National Advisory Council for Healthcare Research and Quality provides advice and recommendations to AHRQ's Director and to the Secretary of the Department of Health and Human Services, on priorities for a national health services research agenda. The 24-member panel comprises 17 private-sector experts who contribute a varied perspective on the health care system and the most important questions that AHRQ's research should address in order to promote improvements in the quality, outcomes, and cost-effectiveness of clinical practice. The private-sector members represent health care plans, providers, purchasers, consumers, and researchers.

Also serving in an ex-officio capacity are principal representatives of seven Federal agencies that address health care issues:

The National Institutes of Health (NIH).

The Department of Defense (Health Affairs) (DoD).

The Centers for Disease Control and Prevention (CDC).

The Department of Veterans Affairs (VA).

The Substance Abuse and Mental Health Services Administration (SAMHSA).

The Food and Drug Administration (FDA).

The Health Care Financing Administration (HCFA).(Agency for Healthcare Research and Quality, 2010)

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COPD as a chronic disease of the pulmonary system

1.- Characteristics, treatment strategies and options for disease management protocols

1.1 Definition

The World Health Organization (WHO, 2008) describes COPD as an umbrella term used to describe chronic lung diseases that cause limitations in lung airflow and progressive damage to lung function.

The more technical definition of COPD, frequently used in the international literature, was provided by the Global Initiative for Chronic Obstructive Lung Disease (GOLD).

GOLD (2008) COPD definition

A preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterised by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases. The chronic airflow limitation characteristic of COPD is caused by a mixture of small airway disease (obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person. Airflow limitation is best measured by spirometry, as this is the most widely available, reproducible test of lung function. Because COPD often develops in long-time smokers in middle age, patients often have a variety of other diseases related to either smoking or ageing. COPD itself also has significant extrapulmonary (systemic) effects that lead to comorbid conditions (Agusti, 2005). Thus, COPD should be managed with careful attention also paid to comorbidities and their effect on the patient's quality of life. A careful differential diagnosis and comprehensive assessment of severity of comorbid conditions should be performed in every patient with chronic airflow limitation.

1.2 Signs and symptoms

The most common symptom of COPD is breathlessness or shortness of breath (dyspnea). Breathlessness in patients initially occurs with exertion and becomes progressively worse over time. Other symptoms of COPD are a persistent cough, sputum or mucus production, wheezing, chest tightness, and tiredness. People with advanced (very severe) COPD sometimes develop respiratory failure. When this happens, cyanosis, a bluish discoloration of the lips caused by a lack of oxygen in the blood, can occur. An excess of carbon dioxide in the blood can cause headaches, drowsiness or twitching (asterixis). A complication of advanced COPD is cor pulmonale, a strain on the heart due to the extra work required by the heart to pump blood through the affected lung. Symptoms of cor pulmonale are peripheral edema, seen as swelling of the ankles, and dyspnea.

The COPD-X guidelines define:

chronic bronchitis as daily sputum production for at least three months of two or more consecutive years; it occurs when repeated lung inflammation damages the lungs, causing

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scarring of the airways and excessive production of mucus, in turn resulting in the characteristic cough. Chronic bronchitis can exist alone, before, or during emphysema and is sometimes present with asthma.

emphysema as a pathological diagnosis consisting of alveolar dilation and destruction. The loss of lung elastic tissue may result in airway wall collapse during expiration and may lead to dynamic hyperinflation – increasing the work of breathing; it develops when many of the small air sacs or alveoli in the lungs become stretched out and lose their elasticity or the ability to empty trapped air. This damage can cause the alveoli to rupture, and form one large air space instead of many small ones. The destruction of healthy air sacs makes it difficult for the lung to work properly as the surface area of the lung exposed to oxygen is significantly reduced. As a result there are fewer alveoli to deliver oxygen to the bloodstream. The damage is progressive and, as lung tissue does not repair itself, the damage becomes permanent.

1.3. Etiology

Smoking is the strongest risk factor for COPD. Research indicates a close relationship between the amount of tobacco smoked and the rate of decline in forced expiratory flow in one second (FEV1). It is estimated that about 70% of COPD in men and 60% in women was attributable to smoking. Not all smokers will develop COPD, but continuous smokers have at least a 25% risk after 25 years. The likelihood of developing COPD increases with increasing age as the cumulative smoke exposure increases.

Genetics: Some factor in addition to heavy smoke exposure is required for a person to develop COPD. This factor is probably a genetic susceptibility. COPD is more common among relatives of COPD patients who smoke than unrelated smokers. The genetic differences that make some peoples' lungs susceptible to the effects of tobacco smoke are mostly unknown. Alpha 1-antitrypsin deficiency is a genetic condition that is responsible for about 2% of cases of COPD. In this condition, the body does not make enough of a protein, alpha 1-antitrypsin. Alpha 1-antitrypsin protects the lungs from damage caused by protease enzymes, such as elastase and trypsin, that can be released as a result of an inflammatory response to tobacco smoke.

Air pollution and occupational exposures: Studies in many countries have found that people who live in large cities have a higher rate of COPD compared to people who live in rural areas. Urban air pollution may be a contributing factor for COPD as it is thought to slow the normal growth of the lungs although the long-term research needed to confirm the link has not been done. Intense and prolonged exposure to workplace dusts, to cotton textile industry and to chemicals have been implicated in the development of airflow obstruction, even in nonsmokers. However, the effect of occupational pollutants on the lungs appears to be substantially less important than the effect of cigarette smoking.

Socioeconomic status: There is evidence that the risk of developing COPD is inversely related to socioeconomic status. Although statistically an independent risk factor, it is not clear whether this reflects exposures to indoor and outdoor air pollutants, poor nutrition, or other factors that are related to low socioeconomic status.

Gender and age: Studies from developed countries show that the prevalence of the disease is now almost equal in men and women, probably reflecting the changing patterns of tobacco

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smoking. COPD is most frequently diagnosed in people aged 40 years or older, although the exposure to risk factors may have occurred much earlier in life.

Autoimmune disease: There is mounting evidence that there may be an autoimmune component to COPD. Many individuals with COPD who have stopped smoking have active inflammation in the lungs. The disease may continue to get worse for many years after stopping smoking due to this ongoing inflammation. This sustained inflammation is thought to be mediated by autoantibodies and autoreactive T cells.

1.4 Morbidity and Severity

Breathlessness causes changes in quality of life and functionality, with the need to adapt activities to help decrease the impact. Physical activities may take longer to complete. A person with COPD may take frequent rest periods in order to be able to complete an everyday activity, such as vacuuming, mowing a yard or cooking a meal. Daily activities, such as walking up a short flight of stairs, or heading out to the shops may become very difficult as the disease worsens, particularly if left undiagnosed and untreated. Quality of life declines markedly and depression is often a comorbidity diagnosed with COPD patients. Four stages of COPD are differentiated:

Stage I: Mild COPD – Characterised by mild airflow limitation (FEV1/FVC < 0.70; FEV1 ≥ 80% predicted). Symptoms of chronic cough and sputum production may be present, but not always. At this stage, the individual is usually unaware that his or her lung function is abnormal.

Stage II: Moderate COPD - Characterised by worsening airflow limitation (FEV1/FVC < 0.70; 50% ≤ FEV1 < 80% predicted), with breathlessness typically developing on exertion and cough and sputum production sometimes also present. This is the stage at which patients typically seek medical attention because of chronic respiratory symptoms or an exacerbation of their disease.

Stage III: Severe COPD - Characterised by further worsening of airflow limitation (FEV1/FVC < 0.70; 30% ≤ FEV1 < 50% predicted), greater breathlessness, reduced exercise capacity, fatigue, and repeated exacerbations that almost always have an impact on patients' quality of life.

Stage IV: Very Severe COPD - Characterised by severe airflow limitation (FEV1/FVC < 0.70; FEV1 < 30% predicted or FEV1 < 50% predicted plus the presence of chronic respiratory failure). Respiratory failure is defined as an arterial partial pressure of O2 (PaO2) less than 8.0 kPa (60 mm Hg), with or without arterial partial pressure of CO2 (PaCO2) greater than 6.7 kPa (50 mm Hg) while breathing air at sea level. Respiratory failure may also lead to effects on the heart such as cor pulmonale (right heart failure). Patients may have Stage IV: Very Severe COPD even if the FEV1 is > 30% predicted whenever these complications are present. At this stage, quality of life is very appreciably impaired and exacerbations may be life threatening.

1.5 Diagnosis

Clinical diagnosis of COPD should be considered in any patient who has breathlessness, chronic cough or sputum production and/or a history of exposure to key risk factors.

Key indicators for considering a diagnosis of COPD are

- breathlessness that is progressive, usually worse with exercise and persistent
- chronic cough, which may be intermittent and may be unproductive and
- chronic sputum production and
- history of exposure to risk factors, i.e. tobacco smoke, occupational dusts, chemicals or smoke.

The sensitivity of physical examination for detecting mild or moderate COPD is poor. Wheezing is not an indicator of severity of disease and is often absent in stable but severe COPD. The presence and severity of airflow limitation are impossible to determine by clinical signs, so objective measurements such as spirometry are essential to diagnosis.

Spirometry is the most effective method to diagnose and monitor the progress of COPD. It measures the forced expiratory volume in one second (FEV_1) which is the greatest volume of air that can be breathed out in the first second of a large breath. Spirometry also measures the forced vital capacity (FVC) which is the greatest volume of air that can be breathed out in a whole large breath. Normally at least 70% of the FVC comes out in the first second (i.e. the FEV_1/FVC ratio is >70%). In COPD, this ratio is less than normal, (i.e. FEV_1/FVC ratio is <70%) even after a bronchodilator medication has been given.

X-ray of the chest may show an over-expanded lung (hyperinflation) and can be useful to help exclude other lung diseases. Complete pulmonary function tests with measurements of lung volumes and gas transfer may also show hyperinflation and can discriminate between COPD with emphysema and COPD without emphysema. A high-resolution computed tomography scan of the chest may show the distribution of emphysema throughout the lungs and can also be useful to exclude other lung diseases.

A blood sample taken from an artery can be tested for blood gas levels which may show low oxygen levels (hypoxemia) and/or high carbon dioxide levels (respiratory acidosis). A blood sample taken from a vein may show a high blood count (reactive polycythemia), a reaction to long-term hypoxemia.

1.6 Therapeutic management of COPD and of acute exacerbations

There is currently no cure for COPD; however, COPD is both a preventable and treatable disease. Clinical practice guidelines for the management of COPD are available from the Global Initiative for Chronic Obstructive Lung Disease (GOLD), a collaboration that includes the World Health Organization and the U.S. National Heart, Lung, and Blood Institute.

The clinical management of COPD has five key components: (1) confirm diagnosis, (2) optimize function, (3) prevent deterioration (4) develop support network and self-management plan and (5) manage acute exacerbations.

CONFIRM DIAGNOSIS

Anyone who reports breathlessness, chronic cough or sputum production or who has risk factors for COPD should be considered for clinical diagnosis using spirometry. A post bronchodilator FEV1/FVC<0.70 confirms the presence of airflow limitation that is not fully reversible. Diagnosis should be accompanied by assessment of the impact of COPD based on

the patient's symptoms, the extent of the lung function abnormality and the presence of complicating factors. The assessment of blood gas tensions should also be considered in patients with an FEV1<50% predicted or clinical signs of respiratory failure or right heart failure. Lower costs and burden of disease can result if diagnosis is achieved early and optimally assessed and treated, as treatment can significantly reduce exacerbations and health care separations associated with COPD.

C: Confirm diagnosis and assess severity	***Evidence level***
▪ Smoking is the most important risk factor for COPD	I
▪ Consider COPD in patients with other smoking-related diseases	I
▪ Consider COPD in all smokers and ex-smokers older than 35 years	II
▪ The diagnosis of COPD rests on the demonstration of airflow limitation which is not fully reversible	II
▪ If airflow limitation is fully or substantially reversible, the patient should be treated as for asthma	

OPTIMISE FUNCTION

Given that COPD is a progressive disease, lung function can be expected to worsen even with the best available care. Pharmacotherapy for COPD has been used to control symptoms, but emerging evidence points to them improving quality of life, increasing exercise tolerance, and in some cases slowing speed of decline. Therefore, pharmacotherapy for COPD is used to optimise function and reduce complications.

- Bronchodilator medications are central to the symptomatic management of COPD. They are given on an as-needed basis or on a regular basis to prevent or reduce symptoms and exacerbations.
- The principal bronchodilator treatments are beta2-agonists and anticholinergics, used singly or in combination.
- Regular treatment with long-acting bronchodilators is more effective and convenient than treatment with short-acting bronchodilators
- The addition of regular treatment with inhaled glucocorticosteroids to bronchodilator treatment is appropriate for symptomatic COPD patients with an FEV1 < 50% predicted (Stage III and IV: Severe and Very Severe COPD) and repeated exacerbations.
- Chronic treatment with systemic glucocorticosteroids should be avoided because of an unfavourable benefit-to-risk ratio.
- In COPD patients, influenza vaccines can reduce serious illness. Pneumococcal polysaccharide vaccine is recommended for COPD patients 65 years and older and for COPD patients younger than age 65 with an FEV1 < 40% predicted.
- Pulmonary rehabilitation reduces breathlessness, anxiety and depression; improves exercise capacity and quality of life and has been shown to reduce hospitalisation.
- The long term administration of oxygen (>15 hours per day) to patients with chronic respiratory failure has been shown to increase survival.

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O: Optimise function	***Evidence level***
▪ Inhaled bronchodilators provide symptom relief in patients with COPD and may increase exercise capacity	I
▪ Long-acting bronchodilators provide sustained relief of symptoms in moderate to severe COPD	I
▪ Long term use of systemic glucocorticoids is not recommended	I
▪ Inhaled glucocorticoids should be considered in patients with a documented response or those who have severe COPD with frequent exacerbations	II
▪ Identify and treat hypoxaemia and pulmonary hypertension	I
▪ Prevent or treat osteoporosis	I
▪ Pulmonary rehabilitation reduces dyspnoea, anxiety and depression, improves exercise capacity and quality of life and may reduce hospitalisation	I
▪ In selected patients, a surgical approach may be considered for symptom relief.	III-2

PREVENT DETERIORATION

The overall approach to preventing deterioration should be individualised to address symptoms and improve quality of life, through health education to improve skills, ability to cope with illness and health status. A key element in preventing deterioration is management of associated risk factors.

- Decreasing the total personal exposure to tobacco smoke, occupational dusts and chemicals, and indoor and outdoor air pollutants are important goals to prevent the onset and progression of COPD.
- Smoking cessation is the single most effective – and cost effective – intervention in most people to reduce the risk of developing COPD and stop its progression.
- Smoking cessation counselling combined with pharmacotherapy are the most effective methods in assisting people to stop smoking
- Comprehensive tobacco control policies and programs with clear, consistent and repeated non-smoking messages can be valuable.
- Efforts to reduce smoking through public health initiatives should also focus on passive smoking to minimise risks for non-smokers.
- Many occupationally induced respiratory disorders can be reduced or controlled through a variety of strategies aimed at reducing the exposure to inhaled particles and gases.
- Reducing the risk from indoor and outdoor air pollution is feasible and requires a combination of public policy and protective steps taken by individuals.
- All health professionals should be encouraged and enabled to become involved in promoting non-smoking messages and supporting community programs that minimize smoking, as well as monitoring work environments.

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P: Prevent deterioration	*Evidence level*
▪ Smoking cessation reduces the rate of decline of lung function	I
▪ General practitioners and pharmacists can help smokers quit	I
▪ Treatment of nicotine dependence is effective and should be offered to smokers	I
▪ Pharmacotherapies double the success of quit attempts; behavioural techniques further increase the quit rate by up to 50%	I
▪ Influenza vaccination reduces the risk of exacerbations, hospitalisation and death	I
▪ Long-term oxygen therapy (> 15 h/day) prolongs life in hypoxaemic patients (PaO_2 < 55 mmHg, or 7.3 kPa)	I
▪ Inhaled glucocorticoids are indicated for patients with a documented response or who have severe COPD with frequent exacerbations	I
▪ Mucolytics may reduce the frequency and duration of exacerbations	II
▪ Inhaled glucocorticoids are indicated for patients with a documented response or who have severe COPD with frequent exacerbations	I

DEVELOP SUPPORT NETWORK AND SELF-MANAGEMENT PLAN

A self-management plan developed in conjunction with the patient's GP and specialist can be useful to indicate how to approach and step-up treatment during exacerbations. The plan should include the development of support networks e.g., through education of carers, other support people and family who may aid in managing COPD. Self management or action plans should have progressive monitoring and review to determine if any modification is required to the treatment recommendations and to identify any complications that may develop over time.

D: Develop support network and self-management plan	*Evidence level*
▪ Pulmonary rehabilitation increases patient/carer knowledge base, reduces carer strain and develops positive attitudes towards self-management and exercise	I
▪ COPD imposes handicaps which affect both patients and carers	II
▪ Multidisciplinary care plans and individual self-management plans may help to prevent or manage crises	II
▪ Enhancing quality of life and reducing handicap requires a support team	
▪ Patients and their family/friends should be actively involved in a therapeutic partnership with a range of professional disciplines	
▪ Patients should be encouraged to take appropriate responsibility for their own management	

MANAGE EXACERBATIONS

Exacerbations are defined as events in the natural course of the disease that are beyond normal day-to-day variations, are acute in onset, and may warrant a change in regular medication in a patient with underlying COPD.

- The most common causes of an exacerbation are infection of the tracheobronchial tree and air pollution, but the cause of about one-third of severe exacerbations cannot be identified.
- Inhaled bronchodilators (particularly inhaled beta2-agonists with or without anticholinergics) and oral glucocorticosteroids are effective treatments for exacerbations of COPD.
- Early treatment with antibiotics where there are clinical signs of airway infection (eg, increased sputum purulence) reduces the severity of the COPD exacerbation and speeds recovery.
- Non-invasive mechanical ventilation in exacerbations improves respiratory acidosis, increases pH, decreases the need for endotracheal intubation, and reduces PaCO2 respiratory rate, severity of breathlessness, the length of hospital stay, and mortality.
- Medications and education to help prevent future exacerbations should be considered as part of follow-up, as exacerbations affect the quality of life and prognosis of patients with COPD.
- Developing self-management or written action plans for responding to worsening symptoms may prevent or reduce severity of exacerbations.
- Emergency department visits and hospitalisation (eg, for respiratory failure) are more likely during acute exacerbations, which can be life-threatening. Hospital mortality for such patients is about 10%, reaching 40% one year after discharge, and higher for patients aged over 65 years. In one study of more than 1,000 patients admitted to several hospitals with an acute exacerbation of severe COPD, about 50% were admitted with a respiratory infection, 25% with congestive cardiac failure, and 30% with no known cause for the exacerbation.
- Exacerbations can also be caused by viral infection and by non-infectious causes, such as left ventricular failure, pulmonary embolus, and possibly other factors, such as air pollution

X: Manage eXacerbations	***Evidence level***
▪ Inhaled bronchodilators are effective treatments for acute exacerbations	I
▪ Systemic glucocorticoids reduce the severity of and shorten recovery from acute exacerbations	I
▪ Non-invasive positive pressure ventilation is effective for acute hypercapnic ventilatory failure	I
▪ Exacerbations with clinical signs of infection (increased volume and change in colour of sputum and/or fever, leukocytosis) benefit from antibiotic therapy	II
▪ Multidisciplinary care may assist home management	II
▪ Early diagnosis and treatment may prevent admission	III-2
▪ ▪ Controlled oxygen in a pre-hospital setting is indicated for hypoxaemia	
▪ Involving the patient's general practitioner in a case conference and developing a care plan may facilitate early discharge	

Levels of evidence are given according to the following scheme:

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- Level I: Evidence obtained from at least one properly designed randomized controlled trial.
- Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

1.7 Medication

Bronchodilators : a group of medicines that relax smooth muscle around the airways, increasing the calibre of the airways and improving air flow. They can reduce the symptoms of shortness of breath, wheeze and exercise limitation, resulting in an improved quality of life for people with COPD. They do not slow down the rate of progression of the underlying disease. Bronchodilators are usually administered with an inhaler or via a nebulizer.

There are two major types of bronchodilator, β_2 agonists and anticholinergics. Anticholinergics appear to be superior to β_2 agonists in COPD. Anticholinergeics reduce respiratory deaths while β_2 agonists have no effect on respiratory deaths. Each type may be either long-acting (with an effect lasting 12 hours or more) or short-acting (with a rapid onset of effect that does not last as long).

β_2 agonists stimulate β_2 receptors on airway smooth muscles, causing them to relax. There are several β_2 agonists available. Salbutamol or albuterol and terbutaline are widely used short acting β_2 agonists and provide rapid relief of COPD symptoms. Long acting β_2 agonists (LABAs) such as salmeterol and formoterol are used as maintenance therapy and lead to improved airflow, exercise capacity, quality of life and possibly a longer life.

anticholinergic drugs cause airway smooth muscles to relax by blocking stimulation from cholinergic nerves. Ipratropium is the most widely prescribed short acting anticholinergic drug. Like short-acting β_2 agonists, short-acting anticholinergics provide rapid relief of COPD symptoms and a combination of the two is commonly used for a greater bronchodilator effect. Tiotropium is the most commonly prescribed long-acting anticholinergic drug in COPD. It is has more specificity for M_3 muscarinic receptors so may have less side-effects than other anticholinergic drugs. Regular use is associated with improvements in airflow, exercise capacity, quality of life and possibly a longer life.

Corticosteroids: act to reduce the inflammation in the airways, in theory reducing lung damage and airway narrowing caused by inflammation. Unlike bronchodilators, they do not act directly on the airway smooth muscle and do not provide immediate relief of symptoms. Some of the more common corticosteroids in use are prednisone, fluticasone, budesonide, mometasone, and beclomethasone. Corticosteroids are used in tablet or inhaled form to treat and prevent acute exacerbations of COPD. Inhaled corticosteroids have not been shown to be of benefit for people with mild COPD however they are beneficial for those with either

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moderate or severe COPD. Most people with COPD who use inhaled corticosteroids also use a long-acting bronchodilator so inhaled corticosteroids are often combined with a LABA in the same inhaler.

Other medication: Theophylline is a bronchodilator and phosphodiesterase inhibitor that in high doses can reduce symptoms for some people who have COPD. More often, side effects such as nausea and stimulation of the heart limit its use. In lower doses, it may slightly reduce the number of COPD exacerbations. The investigative phosphodiesterase-4 antagonists, roflumilast and cilomilast have completed Phase-2 clinical trials. Tumor necrosis factor antagonists such as infliximab suppress the immune system and reduce inflammation. Infliximab has been trialled in COPD but there was no evidence of benefit with the possibility of harm.

Supplemental oxygen: Oxygen can be delivered in different forms: in large containers, in smaller containers with liquid oxygen, or with the use of a oxygen concentrator which derives oxygen from room air. Supplemental oxygen does not greatly improve shortness of breath but can allow people with COPD and low oxygen levels to do more exercise and household activity. Long-term oxygen therapy for at least 16 hours a day can improve the quality of life and survival for people with COPD and arterial hypoxemia or with complications of hypoxemia such as pulmonary hypertension, cor pulmonale, or secondary erythrocytosis. High concentrations of supplemental oxygen can lead to the accumulation of carbon dioxide and respiratory acidosis for some people with severe COPD; lower oxygen flow rates are generally safer for these individuals.

1.8 Mortality and survival rates

According to WHO estimates, 210 million people have COPD worldwide, with one death from COPD every 10 seconds. Total deaths from COPD are projected to increase in the next 20 years, making it the third leading cause of death in the world by 2030 (WHO, 2008), after 'coronary heart disease' and 'stroke and other cerebrovascular diseases'. COPD is also a major cause of death in Europe, and a major source of comorbidities in reported deaths from other diseases, particularly lung cancer and cardiovascular disease. The risk of dying from an exacerbation of COPD is closely related to the development of respiratory acidosis, the presence of significant comorbidities and the need for ventilator support.

2.- Health Political and health economical aspects

2.1 Incidence and prevalence

COPD is very difficult to diagnose and detect clinically in its milder forms without the use of spirometry. Unfortunately, spirometry is not routinely employed in patients at risk for developing COPD (*ie*, smokers), and spirometric test results are not routinely recorded or consistently interpreted. This is due, in part, to the gradual and insidious development of airflow obstruction in COPD and, in part, to absent or nonspecific symptoms that may occur in patients with mild forms of the disease. Along with the difficulty of early detection, the clinician is challenged by the need to distinguish COPD from the persistent airflow limitation of chronic asthma in older subjects. Recent studies appear to indicate that most older adults with asthma have a chronic irreversible component to their disease. The terminology in the field of

obstructive lung diseases is also complex and often confusing, despite several attempts during the last 30 years to define asthma, chronic bronchitis, and emphysema. Diagnostic labels vary by individual physician, by country, and by time period. This makes estimation of the incidence and prevalence of COPD through a review of the biomedical literature extremely difficult, if not impossible, as a number of reports in the literature cite their own definitions of COPD that vary across time and investigation.

With these restrictions, COPD is considered to be a leading cause of death and disability worldwide. It is largely preventable but is expensive to treat. The World Bank estimates that COPD is responsible for > 29 million disability-adjusted life-years and 1 million years of life lost per annum around the world. These figures place COPD as the fifth most significant global health problem, and COPD is expected to become the third leading cause of death in the first quarter of the next century. Furthermore, COPD is currently the 12th leading cause of disability worldwide and is expected to be the fifth leading cause of disability by 2020. However, even these figures may not reflect the true scope of the disease, as there is a relative lack of data available to determine the prevalence and burden of COPD across countries.

Valid data on the prevalence of COPD in Germany are not currently available in published form. The prevalence of chronic bronchitis is estimated in the adult population in Germany to range between 10-15%. The proportion of chronic obstructive bronchitis - cough, sputum and airway obstruction - in the overall prevalence is not precisely known. Since these numbers refer to global data from death certificates and to ICD-9-digits 490 (bronchitis, not specified as acute or chronic) and 491 (chronic bronchitis) a significant underestimation of the mortality of bronchitis must be assumed.

2.2 Healtheconomic burden

Since 1996, hospital statistics show for all obstructive respiratory diseases 2.7 million hospital days in Germany, the vast majority will go to the expense of chronic bronchitis and its consequences. Extrapolated from the data of the AOK, chronic bronchitis causes annually about 25 million out-of-work days, amounting to a economic burden of around 6 billion of euros *(Konietzko N, Fabel H. Weißbuch Lunge 2000. Stuttgart-New York: Thieme; Rulff LK, Volmer T, Nowak D. The economic inpact of smoking in Germany. Eur Respir J 2000; 16: 385-390)*

According to a prospective study with nearly thousand patients, direct costs for COPD will count for 4.50 billion and indirect cost for 3.94 billion euros. The greatest proportion of direct costs are drug costs accounting for 41.4% of, followed with 31.6% by the cost of hospitalization and the cost of medical services with 20.6%. Indirect costs for inability to work account for 45.8%, followed by long-term in-house care with 21.7%. From an economic perspective, the average annual cost of COPD in Germany per patient was estimated at 3027 euro, 26% accounting for hospitalizations, 23% for medications, 17% for early retirement with and 1.5% for rehabilitation. For the statutory health insurance, the cost per patient per year accounts for around 2000 euros *(Rychlik R, Pfeil T, Daniel D et al. Zur sozioökonomischen Relevanz akuter Exacerbationen der chronischen Bronchitis in der Bundesrepublik Deutschland. Dtsch Med Wschr 2001; 126: 353-359; Nowak D, Dietrich ES, Oberender P et al. Krankheitskosten von COPD in Deutschland. Pneumologie 2004; 58 (12): 837-844)*

3.- Research projects and pilot studies as basis for innovative treatment concepts.

3.1 United Kingdom

COPD Project "Better breathing for life". Lambeth and Southwark two primary care trusts and Guy's and St Thomas' and King's College Hospital Trusts. Years: 2007-now

The COPD Project "Better breathing for life" is an innovative scheme that aims to improve care for patients with COPD throughout Lambeth and Southwark. It is based in a collaborative working between the two primary care trusts and Guy's and St Thomas' and King's College Hospital Trusts.(St. Thomas Hospital, 2010)

There are three main arms of the COPD project:

- Early detection and intervention
- Admission avoidance (through the establishment of a 24/7 telephone helpline) and reduction in length of stay by supported discharge for acute exacerbations of COPD (AECOPD)
- Local community multi-professional cluster clinics with provision for PR.

Early detection and intervention. This has been an ongoing theme, which starts from both patient self-management in hospital and community cluster clinics, and runs right through to active and early intervention by the doctors, nurses, physiotherapists and pharmacists in both the acute hospital trusts. There is a slight hospital to hospital variation, but the overall aim is the same.

One of the other ways of achieving early intervention is through changing behaviour by focusing care in cluster clinics, with the intention of prolonging life and quality of life, such as: Moving from dependency to taking charge, Smoking cessation, Taking exercise.

Admission avoidance, 24/7 helpline and reducing stay. The most recent service to be introduced to patients through the COPD Project is the 24/7 crisis telephone helpline.

Prior to the launch of the project, COPD patients were consulted on what services they would most like to see developed. The overwhelming response was to have rapid access to specialist advice at times of crisis. Hence, the helpline service was developed. The specific aim of this service is to safely avoid hospital admission, if not a necessity, through the provision of support and advice to patients over the phone at times of crisis.

Patients are primarily selected for the service by an admission for AECOPD, or are at high risk of this occurring (severe disease in cluster clinic). The service stands alongside the educational package on self-care in AECOPD at pulmonary rehabilitation. The telephones are manned 24/7 by practitioners from nursing, physiotherapy, and pharmacological backgrounds, who have received training in providing telephone support and have experience of home assessment through the accelerated discharge scheme. The practitioner can arrange an ambulance, request an out-of-hours GP visit, or simply arrange to phone or visit the next day depending on their assessment.(St. Thomas Hospital, 2010)

Community cluster clinics. The community cluster clinics are manned by two specialist respiratory nurses, two GPs with a special interest, a healthcare assistant, and a pharmacist.

The clinics are run in primary care, either within individual GP practices or in large practices that act as a 'hub' to several local smaller bespoke practices. So far, the authors have worked with 45 of the 102 practices in the London boroughs of Lambeth and Southwark, and currently work across six practices with another five on the waiting list.

Within the cluster clinics, local expert management reviews are offered to COPD patients of all grades of severity, covering:

- Diagnosis (including spirometry)
- Smoking cessation advice (including carbon monoxide assessment)
- Assessment of suitability of pulmonary
- rehabilitation (with referral, if required)
- Inhaler technique
- Assessment of appropriate drug therapy
- Oxygen assessment (including pulse oximetry).

Primary care teams are fully supported, with the aim of improving standards of care of COPD. The clusters also help to diagnose COPD in those smokers who have not yet had a diagnosis. Diagnosis significantly improves the prevalence data in GPs' COPD registers. The other significant appeal of the cluster clinics is that we are a free service funded by charity and do not count as a referral.(St. Thomas Hospital, 2010)

INFORCE. Nottingham City PCT (NCPCT),

Nottingham University Hospital NHS Trust (NUHT), and the pharmaceutical industry (under the auspices of the Association of the British Pharmaceutical Industry Outreach Programme) (ABPI) and primary care practices in the City of Nottingham. 2007-2009.(Nottingham National Health Service, 2010)

The INFORCE project has been developed in order to lay the foundations for collaborative working between Nottingham City PCT (NCPCT), Nottingham University Hospital NHS Trust (NUHT), and the pharmaceutical industry (under the auspices of the Association of the British Pharmaceutical Industry Outreach Programme) (ABPI) and primary care practices in the City of Nottingham.

The project is in 4 phases - Admissions audit; Recommendations for service development; Implementation of recommendation and solutions; and Evaluation of impact. The Project will run for two years until December 2009

Phase 1 - Understanding the problem, data collection and analysis. This includes the review of the treatment of patients with COPD admitted to Nottingham University Hospitals sites from November 2007 to May 2008. To understand where service and local practice improvements can be made, the project will review the care received by these patients prior to their hospital admission. A specialist respiratory nurse will review the primary and secondary care medical records of all these admitted patients and through the use of a personalised questionnaire, patients will be given the opportunity to describe their own experience of the care they received prior to their admission. The information gathered in this process will then be used to help identify common similarities between admissions, and as a consequence help identify where any potential improvements could be made to local care pathways or treatment guidelines.

Phase 2 - Identifying the solutions and making recommendations. On presentation of the clinical audit findings all stakeholders will have the opportunity to contribute their own thoughts and suggestions for potentially improving local services and guidelines.

Phase 3 - Implementation of recommendations and solutions. Local guidelines and care pathways will be revised accordingly by an expert group and a detailed programme of educational support will be developed for local clinicians, other healthcare professionals and where necessary, patients. Implementation will begin in September 2008.

Phase 4 – Evaluation. The impact of the changes made will be evaluated by a re-audit of admissions over a similar time scale in 2009. The project is managed by the INFORCE Steering Committee, which is comprised of members from each of the 5 member pharmaceutical companies, ABPI, Breathe Easy, Nottingham University Hospital Trust and Nottingham City PCT commissioning, clinical audit and medicines management staff and a GP with Special Interest in Public Health.

The purpose of the project is to audit information on patients with COPD who are admitted to hospital and review whether they have been managed in accordance with best practice as well as develop an understanding of their perceptions of care. This information will enable greater understanding around the factors influencing admission of these patients, and will be used to inform developments (care pathways, guidance, education) in order to reduce the rate of admission to hospital for exacerbations of COPD.

Defence Technology for Health - Chronic Obstructive Pulmonary Disease (DTfH - COPD)

The COPD proof of concept project is designed to trial 3 separate, but integrated, methods of home monitoring. 50 patients have been selected from West Surrey Health Authority. Each patient has a history of acute exacerbations that often lead to hospital admittance. The aim of the trial is to provide evidence to support the clinical view that hospital admissions can be reduced by intervening at an earlier stage during the onset of an exacerbation. COPD is recognised as both a major cause of winter pressures on the NHS, and of premature deaths in the UK. It is also the third most common cause of lost working days through certified illness.

The aims and objectives of the project are:

1. To establish remote respiratory monitoring for patients in the community suffering from COPD.
2. To utilise a 24-hour call centre facility (or 9-5 call centre, with out-of-hours support) for data processing and interpretation.
3. Explore the role of the respiratory nurse specialist to further support care.

The results of the project show that hospital admissions had fallen to around half the anticipated number but, because of the small numbers involved this finding, should be treated cautiously. Patients accepted the monitoring and found the equipment easy to use and the Nestor Healthwatch service reassuring. They felt that their condition was well managed by the service. The experience gained through running this project was transferred to the NHS so that the NHS could continue the service using its own resources.(Telemedicine and e-Health Information Service, United Kingdom, 2010)

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

Chronic Obstructive Pulmonary Disease (COPD) Remote Rehabilitation Classes via video link

Perth and Kinross CHP run COPD rehabilitation courses; these run for 8 consecutive weeks and have recurring funding. The course consists of a multi-disciplinary exercise and education programme. This type of course has been clinically proven to improve quality outcomes for patients with COPD.

Patients living out with Perth city have to travel, in some cases over 50 miles, to get to the class. If they require hospital transport their class can be cut short to comply with the transport schedule. All too often it is simply too far to travel with this debilitating disease.

To replicate the classes face to face in the rural area further investment would be required to deliver the programme. However by developing the video link and using a codec and monitor at both ends for this service, it should allow this to go ahead with very little extra resource and prevent patients and staff having to travel long distances.

A pilot took place between October and December 2008, delivering 16 sessions in the eight week course via a live video conferencing link from Perth Royal Infirmary to Pitlochry Community hospital.

Three patients were at the remote site, linking with the class of twelve in Perth. A skill mix of health care professionals was in place to deliver this course involving a senior physiotherapist and respiratory nurse specialist at the Perth end and a technical grade physiotherapy assistant at the remote end. (The GP's at the remote end were available in the adjoining building, an agreement was in place to attend the class if necessary)

The main conclusion of this project was that the use of tele-health equipment was able to deliver the pulmonary rehabilitation programme. The patients who took part in this trial all had moderate to severe COPD and would not have been able to travel 40 minutes to the main site twice per week to participate in the programme. All staff and patients were in agreement that this was an effective method of delivery for pulmonary rehabilitation and this was reinforced by the clinical findings.

The key issue that this model of delivery addressed was rurality and access. It would appear to be a more efficient method to deliver to these areas.(Scottish Centre for Telehealth, 2010)

Development, pilot and feasibility study for a chronic obstructive pulmonary disease (COPD) specific version of the Expert Patients Programme (EPP)

Developing sustainable self care interventions for chronic illness is a NHS priority. The Expert Patient Programme (EPP) - a generic chronic disease self-management course - will be rolled out to 100,000 people/year by 2012. Whilst the EPP improves patients' confidence, evidence suggests it needs strengthening to achieve its goal of improving self management and reducing health care use. 3 million people in the UK have chronic obstructive pulmonary disease (COPD). To date COPD has proven resistant to self-management interventions. We will develop a COPD-specific version of the EPP strengthened to address patients' specific information needs and incorporating professional disease management advice. Such an intervention would have the potential to promote effective self-management in COPD.

Aims:

To develop a peer led, COPD-specific, self management intervention based on the EPP (known as the chronic disease self management programme, CDSMP in the USA).

To conduct a pilot study of the programme in patients with COPD of varying severity.

To conduct a process evaluation to assess the acceptability and feasibility of the intervention for patients and their carers.

To model the effects and cost effectiveness of the programme.

To use the pilot and modelling data to inform the design of a robust randomised controlled trial (RCT) of the intervention. (NB the funding for this future RCT is not sought in this proposal.)

A COPD-specific version of the EPP informed by meta-ethnographic literature review of COPD patients' disease experience and self management will be developed. This will be refined via a series of patient focus groups.

120 patients with COPD of different degrees of severity from GP disease registers in Barking and Dagenham Primary Care Trust to a pilot RCT of the intervention will be recruited. A mixed methods process evaluation will explore the acceptability, costs and feasibility of the intervention. Patients and their main carers will be followed up for 6 months.

Data collected will be used to model the potential cost effectiveness of the intervention compared to usual care and to design a large robust randomised controlled trial to formally evaluate its effectiveness.

A disease specific version of the EPP designed for patients with differing levels of severity of COPD based on the generic EPP (which is strongly theoretically based) has the potential to prove an effective self management intervention amongst a group of patients with a condition that has hitherto proven very difficult to influence.

Expected impacts are:

- reduced unscheduled health care use,
- improved concordance,
- better quality of life, and
- reduced costs.

This study will also have relevance to other long term conditions by examining:

- the potential of disease specific EPP to influence self management
- the inclusion of traditionally hard to reach patients in EPP
- the sustainability of peer-led interventions delivered by people with a chronic, progressive condition.(Institute of Health Science Education from Barts and The London School of Medicine and Dentistry, 2010)

Project partially funded by the European Commission
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DOC@HOME **"Docobo's flagship telehealth service to enable monitoring, management and self care of patients at home with various long term conditions..."**

doc@HOME is an integrated telehealth solution for the remote management of patients with a range of Long Term Conditions (also known as Chronic Diseases). It is the means for the collection and analysis of essential patient related data, permitting effective management through efficient interaction between clinicians and patients at home.

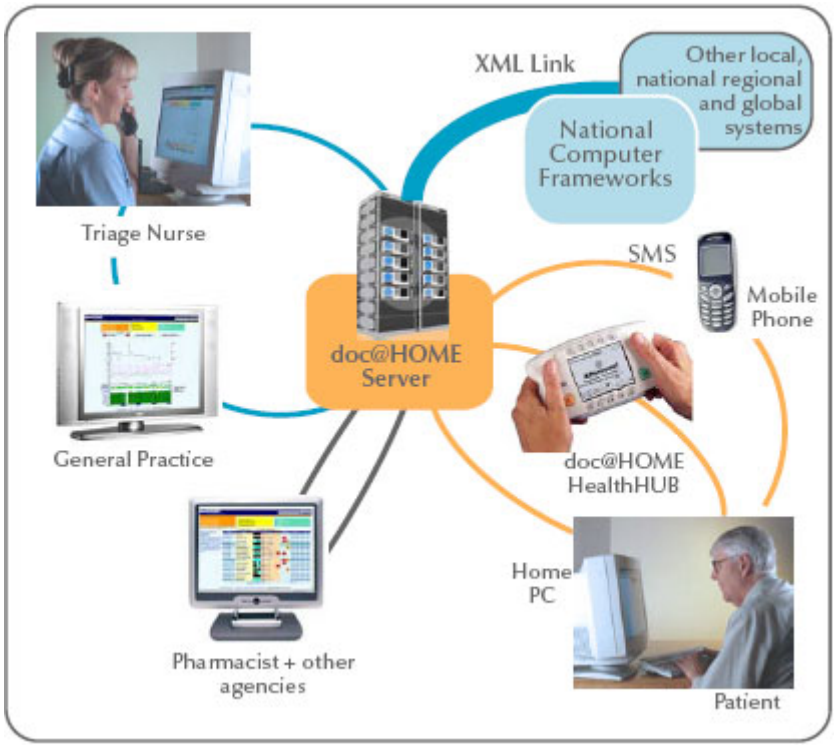

Figure 13.Graphic description of the doc@HOME system.

The doc@HOME service is designed to provide a systematic approach to the management of chronic disease in the home and other locations remote from the clinicians office. Patient/Clinician interaction is typically via the Docobo HealthHub, a fit for purpose, robust, handheld data collection unit which connects through a standard telephone line at the patients home to secure server. Healthcare Professional interaction with the doc@HOME service is via secure Web access using standard browsers, enabling patient management at a range of locations.

Changes in patient trends can be identified and notified to the authorised user. An authorised clinician can access the patient record on demand and send messages directly to the patient, for example, a request to visit the surgery or to change the frequency and/ or volume of medication.(Docobo Ltd. Healthcare Solutions Provider, 2010)

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

Suffolk Primary Care Trust's COPD - Working with Primary Care

Patients with COPD are identified and carefully monitored by their GPs instead of going into hospital. All the 41 GP practices in the chosen area have each been given a £100 Pulse Oximeter, which measures the saturation of oxygen in patients' blood.

The system enables health professionals to keep an eye on patients' blood gasses and can spot people who are likely to have COPD problems in the future. Each practice had a COPD nurse lead and GP lead. Patients were involved from start to finish and took a lead on producing information for patients. There is a leaflet explaining more about COPD, linked with a patient education programme targeted at people's individual requirements. It means if the patient has other long term problems, they are treated together rather than in isolation. Suffolk PCT is aiming to bring standards of care above the QoF in all practices.

With the system, patients with COPD will benefit from early diagnosis and the patient pathway will be simpler.

There was an obvious need to help more patients with COPD. Admission rates of patients with COPD are significantly higher than the regional and national average. Patients were found to be older and sicker on admission and significantly more likely to be readmitted within 90 days after discharge. It is predicted that supporting this service in primary care will reduce hospital admission rates by 22% over the year.(NHS East of England, 2010)

3.1 Spain

Strategy in COPD of the National Health Care System. 2009.

Strategy with the aim of getting a better efficiency and quality in the approach and treatment of this pathology in all the health care services of the public health care system. This strategy includes the following strategic lines: prevention and early diagnosis, care for the chronic patient, care to the patient con exacerbation, palliative care, education for the professionals and research (Ministerio de Sanidad y Política Social, 2009).

Respiratory rehabilitation in COPD. Piloting Hospital Virgen del Camino, Pamplona.

This program aims to promote respiratory rehabilitation in hospitals with existing structures, exporting the program of the Hospital Virgen del Camino (HVC) to patients with inclusion criteria of the other public hospitals in Navarra.

This program implies the development of a pilot rehabilitation program for patients with stable COPD (no exacerbation) moderate - severe, with dyspnea grade II, III, the patients must have stopped smoking or must be in the process of joining a smoking cessation program. The exclusion criteria has been also described. The recruitment of patients was done in the respiratory ward, where they were made a diagnostic testing for their inclusion and exclusion of the program.

Assessment for each patient after the session is made by the development of a quality of life questionnaire and a reassessment that includes running retest and a complete report about the patient health status is also carried out at the respiratory ward.

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Patients are also provided with a custom program made for rehabilitation at home. HVC included in the service discharge report for control and supervision of your doctor (Ministerio de Sanidad y Política Social, 2009).

Multidisciplinary program coordinated between primary care medicine and the hospital to improve the care of COPD: COPD Process

The objectives of this program are:

- To improve the quality of health care for people with COPD coordinating more effectively care levels and specialized primary care.
- To unify criteria for evaluation, treatment and monitoring, regardless of area or clinic to which you refer.
- To streamline the application of existing human and material resources.
- To promote healthy lifestyle behaviours among the unaffected population to prevent the occurrence of new cases.

The program is addressed to patients with COPD

The Project COPD Process is a set of actions from a multidisciplinary consensus among all health professionals in the area of Barcelona assisting people with COPD. Specifically includes pulmonologists and area hospitals, primary care physicians, internal medicine, emergency hospital, palliative care, hospital nursing, primary care and liaison, pharmacists and administrative. Project components:

1. Consensus on the main diagnostic and therapeutic actions among all professionals. A guide in book format and a smaller version with the essential, pocket-sized for a specific hospital professionals were edited, and another one for primary care.

2. Creation of circuits for concrete actions (frequent hospitalization, home-ventilated patients, respiratory rehabilitation program, coordination between levels of care after hospital discharge), with joint participation of professionals from both levels of care.

3. Specific training programme for doctors and nurses, primary care physicians and hospital (Pneumology, Emergency and Internal Medicine).

4. Training program, monitoring and quality control of spirometry in primary care, from the Lung Function Unit of Pneumology Service of the Hospital.

5. A common program for patients´ education for primary and specialized health care.

6. A prescription drug pact between all professionals including hospital pharmacists and primary care.

7. Elaboration of a software for monitoring patients with COPD for Primary Care, incorporated into custom software, used by them for all in Catalonia (e-CAP).

8. Project inclusion among the goals with economic incentives (Management by Objectives-MBO-) in primary care (medical and nursing).

Rating: It aims to determine the effectiveness and impact of the intervention in the health area. This is a quasi-experimental study that provides an assessment or collection of data, pre

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and post-intervention after two years of its implementation. Control group was used as a sample of COPD patients, randomly selected, but from other health areas of Barcelona, the SAP Mountain, where there has been implanted Process COPD.

The information is collected at two levels:

- From clinical information systems and administrative health centres involved.
- Collection of data prospectively in a cohort of 416 randomly selected COPD patients.

The study's major variables are the consumption of health services, particularly hospitals (in emergency department attendance and hospitalization for exacerbation) and quality of life for patients (through the questionnaire CRDQ). Currently it has finished collecting data from the first analysis before surgery and has begun its analysis (Ministerio de Sanidad y Política Social, 2009).

Efficacy of a specific program for patients with COPD who have frequent exacerbations.

Objective: To evaluate the efficacy of a specific program (PE) for patients with COPD who experience frequent exacerbations.

Target **Population:** COPD Patients suffering multiple exacerbations / hospitalizations.

Description: A prospective, randomized, controlled one-year, which compared the efficacy of PE compared with conventional therapy (CT) in a group of frequent exacerbations (3 or more exacerbations per year). This program consists of conducting a thorough and frequent clinical controls accompanied by an educational program to maximize the treatment, improve and promote self-fulfillment. Comparisons are made in various intra-and inter-group care settings, dyspnea, quality of life related to health (HRQOL), inhalation technique and lung function.

Rating: This includes 26 patients (all men), mean age 73 ± 8 years and FEV1 (%) of 43 ± 15%. Exacerbations that required hospital care (emergency visits and / or hospitalizations) decreased in both groups, 24.4% (PNS) in the TC group and 44.1% (p = O.O7l) in the PE group. Hospitalizations were reduced by 73.3% in the intervention group, while they increased by 22% in TC (p <O.001). The days of hospitalization decreased by 77.3% in the EP, growing at nearly twice for the TC (p = 0.014). Dyspnea, HRQL, and the inhalation technique improved in both groups. FEV1 presented once every 46 ml / year in CT group, whereas increased 10 ml / year for PE group (PNS).

Thus the use of a simple program involves a significant reduction in the number of hospitalizations, and perhaps most HRQL better prognosis.

Institution and centres responsible for the intervention or program: Department of Health 08 of the Valencian Community (Lung Unit - Internal Medicine Service General Requena Hospital) (Ministerio de Sanidad y Política Social, 2009).

Home care program of respiratory illness (ADER)

Objective: To provide home treatment of chronic respiratory diseases exacerbated after early hospital discharge in this way for the patient to feel more comfortable and also to reduce the average stay therapy (increasing the availability of hospital beds)

Target Population: Patients with exacerbated chronic respiratory diseases, mainly COPD requiring admission.

Description: In patients with COPD exacerbations is standard treatment regimen according to national and international regulations. Once stabilized and when they do not require intravenous therapy, within 2-4 days of hospitalization, given the high (early) and will continue to try at home to overcome the acute episode. Patients are visited by a nurse every day and in the case of worsening was consultation with the pulmonologist. If the deterioration is severe decides hospital readmission. Once the episode of exacerbation a pulmonologist at the hospital gives you high and referred to outpatient or primary care.

Rating: It was decreased hospital stay (5.9 ± 2.8 versus 8.0 ± 5.1 days, p <O.001). The readmission rate was very low 1%. The reduction in average length of stay resulted in greater availability of beds

Institution and centres responsible for the intervention or program: Pneumology Service. Hospital Universitari Son Dureta. Palma Mallorca. Servei de Salut de les Illes Balears (Ib-Salut). Conselleria de Salut i Consum (Ministerio de Sanidad y Política Social, 2009).

Clinical pathway for patient care with exacerbation of COPD that required hospital admittance.

Objective:
To evaluate the initial performance of a clinical pathway (CP) for inpatient care for exacerbation of COPD.

Target population: Patients hospitalized for COPD exacerbation in a first-level hospital care.

Description: In a first phase, a CP for COPD exacerbation (E-COPD) adjusted to the scientific evidence was developed, tailored to the realities of central and agreed upon by all participants. This CP consisted of:

a) a standard protocol (diagnostic and therapeutic) called "clinical guidelines",

b) performance matrices governing temporary assistance

c) variations in leaf

d) note for the sick person and

e) satisfaction questionnaire.

All patients with COPD who required hospitalization for an E-COPD should continue this VC. Exacerbations are excluded due to pneumonia, pulmonary embolism, pleural effusion and pneumothorax. We performed a prospective study during the first 6 months of operation of the VC. It shows the number of exitus and intubations, revenue in ICU, hospital stay and readmission (<30 days). It also analyzes the treatment received, variations and degree of satisfaction of the sick person. The results are compared with a retrospective series (SR) of all hospitalizations for COPD treated in our hospital during the 6 months prior to the start of the CP.

Rating: In the prospective series will include 50 income from 45 patients, mostly men with a mean age ± SD of 74 ± 8 years. The VC was followed in 19 revenue (38%) in 8 (16%) applied the guidance and in 23 (46%) no protocol was not followed. In the SR 81 revenue collected for 66 patients, one woman (1.5%) and the rest are male (98.5%) with an age of 73 ± 11 years. One patient (5.3%) died in the CV group, whereas in the SR there were 6 deaths (7.4%) (NS). Seven

(8.6%) were admitted to the ICU sick and 5 (6.3%) required intubation in the SR. In the CV group, no case require intubation or ICU admission (NS). The duration of hospitalization was lower in the VC group, but without reaching significance (5.8 ± 3.3 vs. 6.5 ± 4.6 days). Among the cases discharged, the proportion of readmissions was similar in both groups (5.5% in the VC vs. 5.7% in the SR, NS). In the CV group taking antibiotics and nebulizers was reduced by 20.5% and 13.5% respectively, although neither reached statistical significance. The total number of variations was 108, with most attributable to health care workers (57.5%). The degree of satisfaction was high, with an overall score of 85.4% dei.

Conclusions: The initial implementation of a CP for patients hospitalized for COPD at our centre appears to be associated (although not reaching significance) with fewer major complications (intubation and ICU admission), a shorter hospital stay, a lower consumption of antibiotics and nebulizers, and a high degree of satisfaction. However, the completion rate is still very low and the high percentage of variations, so the process is still far from being stabilized

Institution and centres responsible for the intervention or program: Department of Health 08 of the Valencian Community (Unit Respiratory Medicine Department of Internal Medicine, General Hospital Requena)(Ministerio de Sanidad y Política Social, 2009).

Day Hospital in Pneumology.

Objective: To create a new unity, the day of Pneumology Hospital, for the prompt attention in hospitals of patients with exacerbated chronic respiratory disease, especially COPD.

Target population: Patients with chronic respiratory disease as diagnosed by the Service of Pneumology, and having open story in the hospital with evidence of worsening with no signs of severity (RR> 30 rpm, use of accessory muscles, hypotension, altered mental status awareness, etc.).

Description: Creation of a unit staffed Monday through Friday from 8:00 to 15:00 am, located in the hospital, adjacent to conventional ward, which consists of 2 rooms (office and examination room and treatment room). The unit is staffed by a full-time nurse and a part-time Pulmonologist. There are 2 ways of referring patients to it (provided by telephone contact): the primary care physician who regularly follow the sick, you can send the unit for assessment and / or the patient may in turn seek care through a contact number that is given to all patients with chronic respiratory disease are followed regularly in respiratory ward. Before starting up in unity meetings were held with primary care physicians in order to explain the workings of it and the referral criteria

Rating: Retrospective, descriptive of the first consecutive 168 patients treated at the unit. The median age was 67 ± 14 years (range 13-91). Thirty-eight patients were admitted in the past 5 years, the rest had an average of 3.5 hospital admissions in this period (27 patients had been admitted 5 or more times in the past 5 years). Sixty-one patients had not come to the emergency room the previous year, the remainder had attended an average of 2.3 times to emergencies in this space of time (22 subjects were treated at 3 or more times in emergencies).

The most frequent diagnosis was chronic airflow obstruction (COPD or asthma) (64%).

Patients remained in the unit an average of 1.4 ± 0.9 hours (0.5 to 5 hours) (138 patients were in the unit within 3 hours). 19% of the cases had Sa02 c 90% on arrival to the unit. The treatments were the most commonly used bronchodilators (usually administered by nebulisation) and oxygen therapy.

After being treated at the unit, 158 patients were discharged to their address, and the remaining 10 were admitted. In this second group of subjects, the most common diagnosis at discharge from the unit was the chronic airflow obstruction (OCFA) (6 cases), followed by respiratory failure unspecified causes (2 cases), pneumonia (1) and sclerosis lateral sclerosis (1). Seven of the 10 patients admitted to the emergency had not come the previous year, and 6 had been admitted the previous 5 years.

In **conclusion**, most patients seen in the previous unit was a pattern of high consumption of hospital resources. The most common pathology is the OCFA. The vast majority of cases resolve within 3 hours, and 94% of patients are discharged home. Patients admitted are generally those with prior history of increased consumption of hospital resources. It is, in short, an efficient system for managing chronic respiratory disease, which allows the ambulatory management of most of the cases treated, despite a not insignificant percentage of respiratory failure on arrival to the unit.

Institution and centres responsible for the intervention or program: Pneumology Service. Xeral Hospital Complex-Calde (Lugo)(Ministerio de Sanidad y Política Social, 2009).

Continuity of care programme for advanced chronic respiratory disease patients. Programme RESC.

Objectives:

- To ensure comprehensive and multidisciplinary care, care continuity and coordination between different levels of care for advanced COPD.
- To improve the quality of life of advanced COPD and autonomy through the improvement of dyspnea, exercise capacity, educating the patient regarding their disease and optimum utilization of resources and technologies: respiratory rehabilitation program
- To maintaining continuity of care and accessibility to appropriate more resources through H. Day, Nurse Liaison and support to home care through a team of ESAD-Respiratory.
- To develop an approach to smoking, with the objective of both the smoking cessation, and the reduction of consumption and damage, as appropriate.
- In the terminal period of the disease, the patient needs and their environment from the perspective of hospice programs.
- To register the characteristics of patients and health care activity, and evaluated to a greater understanding of advanced COPD and their care needs.

Target population: People with advanced COPD, with high dependency and attendance of health services, which meet one or more of the following points:

- That they have stated two or more hospital admissions last year.

- With chronic respiratory failure and home oxygen, or requiring any other health technology: non invasive ventilation, aerosol, etc.
- In the predominant dyspnea despite following conventional treatment. Physiotherapy techniques that require special or individualized.
- Stadiums terminal illness. Palliative care.

Description: RESC Program is a program of hospital based continuum of care at the Hospital Joan March, which receives patients from acute hospitals in Mallorca, previously assessed by the hospital support teams (UVASS). Those who meet the criteria were proposed for inclusion in RESC Program.

The program is designed with the aim of meeting the needs of the patient's respiratory high dependency on health resources, where possible outside the hospital, through outpatient medical and nurse frequently, offering outpatient respiratory rehabilitation, telephone accessibility through the liaison nurse, the coordination between levels of care and attention on the patient's home through the support team ESAD-Respiratory. All activity is based on the pursuit of comprehensive care through interdisciplinary team.

Rating: By including the patient in the program, a comprehensive evaluation that includes history, tests, assessment of knowledge, quality of life and others is performed. This assessment is repeated every 6 months, recorded and processed by SPSS.

Since the program began in 2002, there have been several assessments of the areas that we considered most interesting:

- Care Plan: There was significant improvement (p <O.05) in the 4 areas of dependency (Virginia Henderson) and respiratory quality of life (SGRQ) after implementation of care plan.
- Nursery consultation and liaison nurse, get significant improvement in management of therapeutic devices, compliance, specific quality of life and reduced hospitalizations.
- Ambulatory respiratory rehabilitation program: in 72 patients with severe and very severe COPD. Are seen with significant improvements (p <O.05) in pre-post RHB: Index BODE, Progress Test 6 ', according to Borg scale dyspnea and CRQ, quality of life in all areas of the CRQ, number of hospitalizations, hospital stay and exacerbations.

Monitoring of 120 COPD were included in the program by having established 2 or more hospitalizations in previous year (mean 3.2) and an average length of stay of 48.12 days. The trend over the two years of monitoring in RESC program is shown in the figures below.

Based on existing literature, the costs for hospitalization of 120 patients the previous year (3rd level hospitals), was 2 million E. and the next two years (hospital 2 ° level) of 1 million E. per year.

Institution and centres responsible for the intervention or program: Hospital Joan March (Mallorca), Health Management de Mallorca (GESMA). Servei de Salut de les Illes Balears (Ib-Salut). Conselleria de Salut i Consum (Ministerio de Sanidad y Política Social, 2009).

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

3.3 United States of America.

COPDGene Study

Background:

The COPDGene® Study is one of the largest studies ever to investigate the underlying genetic factors of Chronic Obstructive Pulmonary Disease or COPD. The COPDGene® Study is looking for answers to why some smokers will develop COPD and others will not. While it has been demonstrated that cigarette smoking can cause COPD, only a minority of smokers develop this debilitating disease thus raising the question of genetic susceptibility. Through the enrollment of over 12,000 individuals, the COPDGene® Study aims to find inherited or genetic factors that make some people more likely than others to develop COPD. With the use of CT scans, COPDGene® also seeks to better classify COPD and understand how the disease may differ from person to person. Currently the COPDGene® Study is recruiting both smokers and non-smokers between the ages of 45 and 80. (COPDGene, 2010)

The COPDGene® Study has 21 clinical sites throughout the country ranging from UCLA in California to Duke University in North Carolina. The vision for the COPDGene® Study was realized by Dr. James Crapo of National Jewish Health in Denver Colorado and Dr. Edwin Silverman of Harvard University's Brigham and Women's Hospital in Boston Massachusetts. Through continuing collaboration with physicians and researchers across the country, COPDGene® continues to expand and discover exciting new information on the development and progression of COPD. They are currently recruiting individuals at all 21 clinical sites to participate in our study and help us learn more about COPD.(COPDGene, 2010)

Methods:

Study Design

Specific Aim 1: Cohort Building. The enrollment of 12,000 subjects is balanced with 2/3 non-Hispanic White and 1/3 African American, distributed across the full spectrum of disease severity and both genders (Table 4). The cohort is specifically being recruited for a genome wide association study (GWAS) analysis and is large enough to provide adequate statistical power to detect genes exerting modest effects on risk.

Specific Aim 2: Characterization of Subtypes of COPD. The main characterization of COPD subtypes will be based on the presence and severity of parenchymal and airway disease based on inspiratory and expiratory high-resolution chest CT scans.

Specific Aim3: Genome-Wide Association Study (See Figure 2). The initial study plan for the GWAS involves four phases. There will be an initial GWAS on a balanced group of 3000 subjects of current or former smoker case and control subjects (2000 White and 1000 African American) in Phase 1. Statistical signals (SNPs in or between genes) identified in Phase I will be confirmed in Phase II with a custom SNP array that will provide greater coverage of genes. In Phase III SNPs in genes/regions identified and confirmed in Phases I and II will be investigated with regional fine mapping and tests of associations to identify causal genes. The final group of candidate genes will be replicated in other COPD cohorts as Phase IV. With continued improvements in SNP genotyping technology additional phases (beyond Phase 1) may be analyzed at the genome-wide level.

Specific Aim 4: Natural history of COPD and Risk Factors for Progression. The COPDGene cohort will be established for longitudinal follow-up with regular contact made to determine mortality, comorbid disease events and disease status based on clinical and/or chest CT evidence of progression.

Population:

Twenty one clinical study centers (See appendix 1) throughout the United States are enrolling participants under this protocol over a four year period. Each study site has obtained local IRB approval to enroll participants in this project and all subjects provide informed consent to participate in the study.

Inclusion and Exclusion Criteria:

The primary inclusion criteria are self-identified racial/ethnic category as either non-Hispanic whites or African-American between ages of 45 and 80 years. All COPD cases and smoking controls reported at least 10 pack years of smoking and could be current or former smokers. Non smoker controls are also included in the study. The age range is 45 to 80 years. Subjects over age 80 are excluded. Pregnant women are excluded because CT scans are part of the study protocol and represent an unacceptable risk to a fetus. History of other lung disease except asthma (e.g. pulmonary fibrosis, extensive bronchiectasis, cystic fibrosis), previous surgical excision of at least one lung lobe, active cancer under treatment, suspected lung cancer (large or highly suspicious lung mass), metal in the chest or recent exacerbation of COPD with antibiotics or steroids are exclusion criteria. Subjects with recent COPD exacerbations can be enrolled one month after their exacerbation.
Smokers who have an unclassified pattern by GOLD criteria on spirometry, denoted as GOLD U (normal FEV1/FVC but reduced FEV1) are eligible for the study but will be analyzed separately. Since a key goal of this project is to define COPD phenotypes in the most complete manner possible, this group of participants was retained to allow the full breadth of smoking related lung disease to be studied.
Individuals diagnosed with asthma, in either the COPD or smoking control groups, are included in COPDGene®. COPD subjects are often diagnosed with asthma, and therefore excluding asthmatics would not provide an accurate distribution of COPD subjects. Both case and control groups will be monitored throughout the study for numbers of asthmatics (as defined by report of physician diagnosis of asthma or bronchodilator response on spirometry) in each group and data analysis both with and without asthmatics will assess the impact of the asthma phenotype on inferences from our genetic analyses.

Imaging:

CT scans are acquired using multi-detector CT scanners (at least 16 detector channels). Volumetric CT acquisitions are obtained both on full inspiration (200mAs), and at the end of normal expiration (50 mAs). Image reconstruction utilizes sub-millimeter slice thickness, with smooth and edge-enhancing algorithms. Detailed CT protocols are provided in Appendix 2.

Data Collection:

Each study subject has pre- and post-bronchodilator spirometry performed using a standardized protocol and spirometer (ndd EasyOneTM Spirometer, Zurich, Switzerland). Information collected from each subject includes a modified American Thoracic Society (ATS)

Respiratory Epidemiology Questionnaire, demographic information; medications, medical history, and St George's Respiratory Questionnaire (SGRQ) (see full data collection forms on COPDGene web site at www.COPDGene.org). Height, weight, blood pressure and oxygen saturation are also assessed. A standardized six minute walk test is performed on each subject. Inspiratory and expiratory CT scans are done with defined protocols produces images that permit measurement of airway wall thickness and the extent and distribution of emphysema. A blood sample for DNA is obtained from each subject; DNA, serum and plasma are stored for future biomarker studies at the COPDGene® Biorepository at John Hopkins University.

Recruitment:

Recruitment of adequate numbers of subjects distributed between controls and four COPD GOLD stages is a key factor for success of this study but poses a logistical challenge. Recruitment by age, gender, race, and disease status for each clinical study center is monitored on a real-time basis by the Data Coordinating Center (DCC). Regular review by the Administrative Core and Executive Committee allows the study as a whole to monitor recruitment in specific groups as needed. A Certificate of Confidentiality from the US Department of Health and Human Services was obtained at the onset of the study to provide additional protection for the research participants and their subsequently generated data on genetic markers.

Data Management:

All study data are ultimately stored in the COPDGene Data Coordinating Core (DCC) at the Division of Biostatistics and Bioinformatics at National Jewish Health. Data are entered by each site through a web-accessible system. Verification of eligibility is completed via a website questionnaire after subjects sign the research consent form, and subjects are tracked for completion of all study data. If a participant is excluded or discontinues during or after the study procedures, the specific exclusion or discontinuation reason is recorded in the database.

Pulmonary Function Test (PFT) Core

The objective of the PFT Core is to ensure pulmonary function data are of the highest quality by device specification, technician training, and standardized protocols. All spirometry data are collected using the ndd EasyOne Spirometer (Zurich, Switzerland). It is an ultrasound-based spirometer utilizing a dual beam Doppler approach to flow measurement and has Windows-based software program to collect, calculate and store final spirometry data.

Imaging Core

The Imaging Core is centered at National Jewish and works on a collaborative basis with the Iowa Comprehensive Lung Imaging Center at the University of Iowa and imaging staff at the Brigham and Women's Hospital. Research assistants log receipt of images, perform quality analysis, coordinate required readings, and assist with quantitative analysis. De-identified images are submitted on DVDs to the Image Core in DICOM format, using a study ID as the only identifier.

Sample Storage Core

The Sample Storage Core at Johns Hopkins University coordinates blood sample shipments and storage using barcode labels and the Freezerworks database to track samples through intake and processing to serum, plasma, and DNA. It also provides an inventory of the complete sample storage for the project. Each subject has a minimum of 50 micrograms of DNA stored along with additional aliquots of stored buffy coat, plasma and serum.

Training of Study Centers:

An initial training program was developed to insure constant data quality across the clinical study centers. There were six major areas identified for training: spirometry, subject data collection and data entry, participant eligibility, safety assessment and functional tests, CT scans and blood/DNA collection and shipping. Training programs were made available on the study website for each site to train new coordinators. Spirometry skills were assessed after the formal training by requiring each coordinator to submit test values and flow curves on 3 naïve subjects. Radiology technicians were trained at their local sites by a web based program describing CT scan methods, to provide uniformity in verbal instructions to subjects, performance of the CT protocol, and management of CT data.

Each Clinical Center was individually assessed for completion of all training activities. After obtaining final IRB approval for the project, the Clinical Center director and coordinator(s) participated in a teleconference with the administrative core to initiate activation of the Clinical Center. Two pilot subjects were enrolled at each site and subject data collection, data transfer, CT methods and shipping procedures were reviewed and approved prior to beginning full enrollment.

Quality control:

Each of the study Cores (PFT, Imaging, Biorepository, Genome Wide Analysis, Candidate Genotyping, and the DCC) developed plans for quality control of data handling. The DCC is the central storage site for all study data and leads the QA program for data entry, including range-checking of data on entry, multi-variable validation and monthly reports on data quality, and maintenance of an auditing record of all data changes. Each study center is informed weekly about out-of-range data so problems can be resolved rapidly. Data identified as out of range are reviewed by the Quality Control Committee and when necessary by the Adjudication Committee.

CT scan quality control

Quality assurance of CT images is multi-level. Each CT scan is visually inspected by the local clinical radiologist for adequate inspiration, absence of motion artifact, and inclusion of all parts of the chest. At the Imaging Core, a trained Professional Research Assistant evaluates the scan for technical completeness, compliance with protocol, adequacy of inspiration, and presence of motion artifact. The quality of the automated segmentations of airways is verified. Finally, the stability of CT measurements for each scanner used in the study is monitored by monthly scanning using a custom COPDGene phantom designed for this study.

Analysis:

Phenotypes:

A large amount of phenotypic information is collected from study participants. To minimize the substantial multiple testing problems in our GWA analysis, we will focus on four key phenotypes for analysis.

1. Status of COPD - defined as GOLD Stages 2-4 in smokers. The absence of COPD is determined by normal spirometry in smokers.

2. Airflow obstruction (post-bronchodilator FEV1 - used as a continuous variable in COPD cases)

3. Emphysema (% of lung <-950 HU - used as a continuous variable in COPD cases)

4. Air trapping on expiratory CT (% of lung < -856 HU - used as a continuous variable in COPD cases)

5. Airway disease - wall area percent of the 4th and 5th generation airways.

CT phenotyping:

The following analyses are performed on segmented lung images, using VIDA software (VIDA Diagnostics, http://www.vidadiagnostics.com): total inspiratory and expiratory lung volumes, mean lung attenuation, and relative lung volumes (for the whole lung, and for each lobe) falling below attenuation thresholds of -950, -910 and -856 HU. Emphysema distribution is assessed by comparing percent emphysema in central vs. peripheral lung and upper vs. lower lobes. Automated airway segmentation and quantification are performed, as discussed by Hoffman et al 7. For each bronchial tree, multiple parameters are calculated for third, fourth, fifth, and sixth generation bronchi, including wall area, lumen area, wall thickness, and luminal diameter.

Genetic analysis plan:

COPDGene® will apply three general analytical strategies for the genome-wide SNP data to both maximize statistical power in identifying disease susceptibility loci (DSL) and minimize false positive results. 1. Immediate Identification of DSL achieving genome-wide significance (using methods for screening and testing in the same dataset 18), 2. Ranking SNPs based on estimated effect size for 2-Stage design, 3. Combining results across racial groups through either meta-analytic techniques or by incorporating covariates that summarize genetic background.

Genetic association tests will be performed for both qualitative and quantitative COPD-related phenotypes. Separate association analysis will be performed in the GOLD Stage 1 subjects and GOLD-U subjects to see if these subsets have significantly different distributions of disease-associated alleles and/or haplotypes compared to those seen in other GOLD Stage subjects.

Data Sharing:

The resources and the results of the COPDGene® study will be made available to other investigators in a manner that will allow the broad scientific community to benefit from the work of this project while protecting the privacy and confidentiality of research subjects. The data sharing plan is to provide all datasets (including genotype and phenotype data) to dbGAP

(http://www.ncbi.nlm.nih.gov/sites/entrez/dbgap) as soon as possible after the data is verified to the standards described in the QC section above.

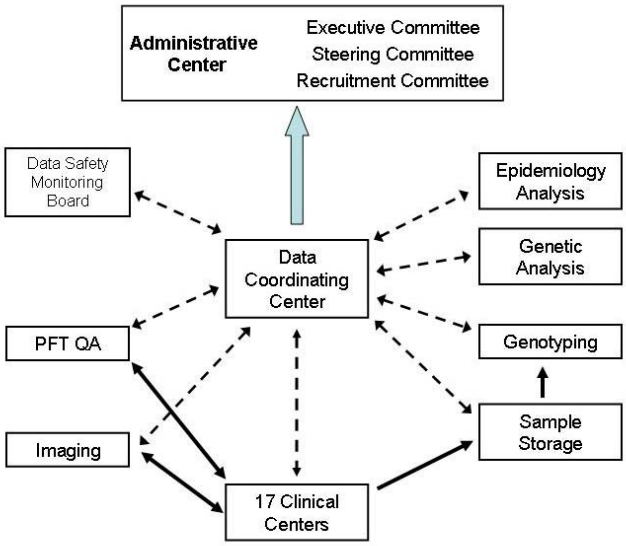

Figure 14. Graphic description of the COPDGene® system.

Discussion:

We anticipate that COPDGene® will generate a unique, large cohort of well-phenotyped subjects for COPD research. The high level of phenotypic characterization will provide a valuable resource for studies into the genetics, epidemiology, and natural history of COPD. The genome-wide association (GWA) approach chosen for COPDGene® has the potential to identify genes influencing risk for complex diseases in a systematic and unbiased manner without relying on our currently limited knowledge of pathophysiology to select candidate genes. Moreover, association studies may be able to detect genes of modest effect that cannot be identified using conventional linkage analysis [15]. The rapidly expanding array of successful GWA studies demonstrates that this approach has potential to provide new insights for complex diseases like COPD [14].

The relative importance of common vs. rare variants in the etiology of complex diseases remains a subject of some debate. Common genetic variants are likely to contribute to the control of complex diseases, although their individual effects on risk may be quite modest, and furthermore multiple genes are likely to be involved. Rare genetic variants are also likely to contribute to risk, and while their individual effect may be larger, their rarity in the population makes it difficult to identify and confirm their effects in case-control designs. Identification of very rare genetic variants is not practical using genetic association analysis because of the extremely large sample sizes needed; however, the sample sizes proposed in this project will

enable us to identify relatively rare alleles (e.g., allele frequency as low as 0.05) associated with moderately increased disease risk. A major limitation of GWA analysis in a single phase is the unacceptable number of false positive SNPs that will be identified simply due to the extremely large number of statistical tests conducted. The multi-phase study design proposed will specifically to limit false positive findings, while maximizing the number of true positives. Furthermore, we will compare tests within the COPDGene cohort to results from other cohorts and family based studies to replicate our results.
In addition to the analyses of the entire COPDGene population listed above, separate analyses of the GOLD Stage 1 cases will be performed. We will attempt to identify a normal subgroup and an early disease subgroup within this phenotypic category based on their CT emphysema, CT airway, and spirometric characteristics. The relationship of this "normal" subset to functional impairment and disease impact measures will be assessed. We hypothesize individuals in the putative normal subgroup will have less functional impairment, less evidence for disease impact, and fewer exacerbations. Ultimately, longitudinal follow-up will be required to determine if the hypothesized "normal" subgroup of GOLD 1 subjects are less likely to progress to full airflow obstruction. However, cross-sectional analysis of GOLD 1 subjects will determine whether clinical heterogeneity can be discerned within these groups using CT data.
There are several future research opportunities generated by this study that will be important for the general pulmonary research community. First, additional characterization of functional variants in any and all susceptibility genes identified here will be required. This will involve resequencing these genes to identify specific mutations followed by further biochemical or physiologic studies to define the functional impact of these variants using animal models. Second, longitudinal investigation of all cases and controls recruited for COPDGene will provide new insights into the natural history, epidemiology and even the genetic basis of COPD. This would include improved understanding of the GOLD 1 and GOLD U groups, plus assessment of risk factors for COPD progression, morbidity, and mortality.

Conclusion:

COPD is a disease with important public health implications given its often profound effects on functional capacity, quality of life and mortality. At this time there is a dearth of effective disease treatments for moderate to severe disease or effective secondary prevention strategies for early or occult disease. Further progress in these areas is hampered by the long latency period between smoking exposure and development of clinical disease, as well as by a relatively small proportion of smokers who develop symptomatic disease. Wide variation in disease expression patterns (airway disease, emphysema, extrapulmonary effects and patterns of exacerbations) may limit statistical power to detect successful results within these subsets in therapeutic trials.
COPDGene® with its large population and focus on CT phenotypes proposes to define subsets of COPD that may reflect effects of specific genetic variants. Careful CT phenotyping may generate diagnostic imaging biomarkers and permit early disease identification in high risk groups. This early diagnosis of asymptomatic disease will provide new opportunities to develop prevention strategies and treatment to limit disease progression. Available treatments will also spur new efforts to encourage screening for early disease in smokers with continued emphasis on smoking cessation. The genetic associations expected from performing GWAS in this large cohort may reveal novel directions for defining disease mechanisms while

advancing knowledge about basic mechanisms and also providing opportunities for treatment and prevention.
Finally, the wealth of data to be accrued in COPDGene® will be stored and made available to the broader scientific community for future studies. This will include the detailed phenotypic subject information, whole genome data and the imaging data from CT scans.(COPDGene, 2010)

Pilot Study of an Online Dyspnea Self-Management Program for COPD

Abstract

To address some of the shortcomings to providing timely and convenient education and support to patients with COPD, especially in the management of dyspnea, the Internet was considered a viable medium to deliver a previously tested program at a distance to reach more patients. Older COPD patients were able to participate in the program and most were very satisfied with the program. Changes were noted in dyspnea, support, self -efficacy, and exercise.

Background

Approximately 66% of US adults had Internet access in 2002 (Harris Poll) with those in the 50–64 age range as equally represented online as younger users. Although access is still limited for many population segments, the current trend in growth suggests that the Internet will become a pervasive and accessible form of media in the years to come. The purpose of this study was to determine the feasibility, acceptability, and preliminary effectiveness of a nurse-facilitated and peer supported Internet-based dyspnea self-management program (iDSMP) for people with chronic obstructive pulmonary disease (COPD). The iDSMP was modeled after a successful face-to-face (F2F) program1 based on Social Cognitive Theory. Participation in the iDSMP is hypothesized to improve dyspnea, self-efficacy for managing dyspnea, perceptions of social support, and exercise behavior. A second aim of the study was to test whether this medium could serve as an independent intervention or if this technology is more appropriate only as an adjunct to previous F2F contact.

Methods

Two groups were evaluated at baseline and 3 months. Subjects were recruited from a database of patients who had participated in a F2F DSMP, allowing a test of a “booster” effect (n=7). A second group of subjects (n=9) were recruited from all other sources and had no previous relationship with the investigators in order to evaluate the program as a “primary” intervention. Home visits were conducted. The intervention consisted of: 1)Weekly structured self-management education via live text chat. 2)Exercise Monitoring, Goal Setting and Feedback. 3)Pulmonary Function and Symptom Monitoring. Subjects monitor lung function using the Airwatch and data can be uploaded to the site.4) Peer and Professional Communication via chats, bulletin board, and email. Process metrics were tracked over 3mos. Outcomes were assessed online. Descriptives and calculations of effect sizes (xpre − xpost /SDpooled) were performed.

Results

Mean age of iDSMP subjects was 69.1 (range 55–82), FEV1/FVC 41±7%, use of Internet for 5 years, and 4 mos with live chats. Data for both groups were pooled since there were no

differences between the two groups in demographic or usage characteristics and study outcomes. The first month registered the most logins (330) compared to 104 in the final month. 73% reported being very to completely satisfied with the program and that participation increased their access to information. Improvements were noted for dyspnea (effect size (ES)=0.86), self-efficacy for managing dyspnea (0.94), support (0.32), and endurance exercise (0.27) for the overall sample.

Discussion

The findings suggest that older patients with COPD are able to successfully participate in an online DSMP and that certain health outcomes can be improved. Since this study did not have a control group and inadequate power to detect significant improvements, larger controlled trials are needed to confirm these early positive results. Programs like the iDSMP could be helpful adjuncts to regular clinic contacts in promoting successful self-management for a variety of other chronic illnesses.(Nguyen et al., 2003)

Pilot Study of a cell phone-based exercise persistence intervention post-rehabilitation for COPD

Objective:

To determine the feasibility and efficacy of a six-month, cell phone-based exercise persistence intervention for patients with chronic obstructive pulmonary disease (COPD) following pulmonary rehabilitation.

Methods:

Participants who completed a two-week run-in were randomly assigned to either MOBILE-Coached (n = 9) or MOBILE-Self-Monitored (n = 8). All participants met with a nurse to develop an individualized exercise plan, were issued a pedometer and exercise booklet, and instructed to continue to log their daily exercise and symptoms. MOBILE-Coached also received weekly reinforcement text messages on their cell phones; reports of worsening symptoms were automatically flagged for follow-up. Usability and satisfaction were assessed. Participants completed incremental cycle and six minute walk (6MW) tests, wore an activity monitor for 14 days, and reported their health-related quality of life (HRQL) at baseline, three, and six months.

Results:

The sample had a mean age of 68 ± 11 and forced expiratory volume in one second (FEV1) of 40 ± 18% predicted. Participants reported that logging their exercise and symptoms was easy and that keeping track of their exercise helped them remain active. There were no differences between groups over time in maximal workload, 6MW distance, or HRQL ($p > 0.05$); however, MOBILE-Self-Monitored increased total steps/day whereas MOBILE-Coached logged fewer steps over six months ($p = 0.04$).

Conclusions:

It has been showed that it is feasible to deliver a cell phone-based exercise persistence intervention to patients with COPD post-rehabilitation and that the addition of coaching appeared to be no better than self-monitoring. The latter finding needs to be interpreted with caution since this was a purely exploratory study.

General overview:

The purpose of this study was to test the feasibility of using cell phones to support exercise persistence in patients with COPD after pulmonary rehabilitation. Participants were randomly assigned to one of two programs for 6 months, MOBILE-Coached (n=9) or MOBILE-Self-monitored (n=8). The MOBILE-Coached program received more intensive follow-up. We found that all participants (mean age of 68; moderate to severe COPD) reported that logging their exercise and symptoms on the cell phone was easy and that keeping track of their exercise helped them remain active. There were no differences between groups in how well they performed on exercise tests and their quality of life but the MOBILE-Self-Monitored group showed a greater increase in their physical activity compared to the MOBILE-Coached group. These findings should be interpreted with caution due to the small sample size (Nguyen et al., 2009)

3.4 Greece

Throughout the country, there are still under development, or have already ended, research projects and pilot studies related to the Public Health. Some of them are briefly described here.

SmartEyes

In 2006 there was a pilot entitled “SmartEyes”. 100 users in Athens and 50 in Thessaloniki participated during the pilot study. “SmartEyes” is an integrated navigation system for people with partial or total vision loss in the urban environment, which is developed by the Telecommunications Laboratory, Department of Electrical and Computer Engineering, of Aristotle University of Thessaloniki. The pilot study was supported by three major companies, Cosmote, Microsoft and Geomatics.

”SmartEyes consists of a portable handheld computer with Bluetooth audio connectivity and a GPS receiver along with an advanced voice communication system for the user. Equipped with an enriched digital map, the system collects data via GPS, process them and provide the user with all the necessary orientation information through audio messages. In addition, exceptional audio messages warn the user while approaching places such as bus stops, traffic lights, buildings etc. The instructions also include public transportation accessibility (buses, metro, tram etc.); guiding and informing about what attitude should be taken until the person reach the desired destination. Points of interest (public services, recreation areas, museums, cafe, restaurants, etc.) are available to the user at any time of the trajectory of the road. The abovementioned pilot program completed successfully in 2006 and also received the "Audience Award" for visually impaired people of the report "European Marketplace on Corporate Social Responsibility".

Pilot program of telemedicine provided by Vodafone

Doctors and nursing staff from various Greek municipalities are members of the inter-municipal Health Network of Social Solidarity. Across the country, 4 specialized doctors from the clinic “Medical Athens” engaged in the pioneering "Telemedicine" pilot program which makes use of telemetry systems. After the recommended training, doctors and nurses are equipped with recording devices such as electrocardiographs, spirometers, oximeters, sphygmomanometers and glucometers connected with PDA devices.

Training process is done by organization and support of Vodafone. With the equipment given to the doctors, is allowed the examination of patients with chronic diseases (cardiograms or respiratory control to examine the possibility of asthma) in any of the Participating regional clinics, and transportation of the results of the tests through - GPRS network of Vodafone to Medical Athens clinic and specifically to a qualified cardiologist and / or pulmonologist, who will take the test results and will send the advice in the same way. The Telemedicine technology-based mobile communications creates multiple benefits for all participants. For the patients is given the possibility to eliminate the geographic restrictions and support the sense of security for the citizens through direct access to specialists. For doctors, a better management of patients is performed since they can provide specialist health services in remote areas without direct access to central hospital, and also have the opportunity to communicate and cooperate with specialized scientific staff of the "Medical Athens" clinic.

After the successful first year of the pilot project "Telemedicine" program has been expanded to 17 clinic regions throughout the country.

3.5 Sweden

Throughout the country and in Europe, there are still under development, or have already ended, research projects and pilot studies related to the Public Health. Some of them are briefly described here.

The Baltic eHealth Project

Many countries in the Baltic Sea region are experiencing the migration of highly qualified medical specialists from rural to urban areas and across national boundaries, as enabled by European Union membership. Cross-border migration is disrupting the labor market; countries like Estonia and Lithuania are losing skilled workers to richer areas like Denmark, where skills shortages and higher salaries are generating attractive career opportunities. A common concern among governments in the region is how to deliver high-quality services to rural and remote areas in a cost-effective manner. To improve information management and knowledge sharing in their healthcare systems, the governments of Denmark, Norway, and Sweden began building national networks in the late 1990s. During that process, it became clear that connecting the networks would facilitate new forms of information exchange and collaboration. Creating a transnational network that connected several countries in the Baltic Sea region could go even further toward helping governments address urgent healthcare issues.

In 2004, health organizations from Denmark, Estonia, Lithuania, Norway, and Sweden set up the Baltic eHealth Project, which was financed in part by the European Commission's INTERREG III B initiative to promote transnational cooperation. The project's objectives include:

• Encouraging the use of e-health (IT-supported healthcare delivery) in rural areas of the Baltic Sea region

• Piloting a cross-border marketplace for the exchange of knowledge-based health services

• Examining the effect of a cross-border marketplace on reducing the migration of skilled labor from poorer to more developed areas

The six municipalities' trial

The SNIPH together with the Swedish National Drug Policy Coordinator made a trial comparing six municipalities that were given support and extra resources in their preventive work, with six matched control municipalities not given this extra support. The aim was to evaluate what difference extra support of prevention make compared to prevention as usual.

This trial is called "the six municipalities' trial" and was presented in the 2003 NR and consisted of four cross-sectional measurements 2003, 2004, 2006 and 2007. An evaluation of the trial showed that no differences could be seen between the six supported municipalities and the six matched controls regarding alcohol and drug consumption13.

The 12 municipalities were not a randomly selected but never the less assessed to be reasonably representative of all Swedish municipalities. It is therefore of interest to compare the prevalence's from that study with the prevalence's reported in the national survey

3.6 Norway

Throughout the country, there are still under development, or have already ended, research projects and pilot studies related to the Public Health. Some of them are briefly described here.

The Baltic eHealth Project

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• Examining the effect of a cross-border marketplace on reducing the migration of skilled labor from poorer to more developed areas

Workflow across organizational borders

There is an increased pressure on health care providers, regarding efficiency as well as quality. Accordingly, there are reiterating ambitions of streamlining health care through notions such as shared care, integrated care, and continuity of care. Continuity of care requires a high degree of interaction and communication between the different organizational levels of the health care system. A system for electronic ordering of laboratory services from primary care to hospital laboratories is under development and implementation in the Norwegian health care system. The system is developed by Well Diagnostics in cooperation with UNN. It is currently being commercialised and implementation in several hospitals in Norway is planned.

The intention with electronic requisitions of laboratory services is to improve the work- and information flow, hence increase quality and reduce workload. The planned large scale implementation of the system at UNN and AHus will enable empirical data that will make it possible to study a wide range of questions regarding the work and information flow and cooperation/interaction between the actors in different health care organisations before and after implementation. The continuous development of the system will make it possible to study the development process as well as the interaction between vendor and users. The main aim of the project is to examine and produce further knowledge on the processes of designing and implementing information systems for collaboration in health care across organisational borders. The study will also identify the impact of such systems on interaction and work processes

3.7 Germany

COSYCONET – German COPD and Systemic Consequences – Comorbidities Network

The project COSYCONET is a current BMBF project, which is designed for the duration of 3 years.

The main goals of the young project are to decline the expenses and the consumption of resources with COPD. Furthermore, the health-related quality of life of COPD patients with different severity is to be be advanced. Therefore population-based controls in profile analysis are to be elated. Also the development of a Markov-model, for modelizing an aetiopatholigy and the expenses in Germany over a long temporal horizon based on this data, is planned.

The specific focus of all analysis is the importance of the comorbidity and its reciprocity with COPD. Such Questions are especially important with chronical illnesses, such as COPD, that stand in relation to comorbidity, which lead to multiple therapies and thereby to reciprocities between the therapies. This subproject will collect this data for germany in a big patients cohort and compare it to a population-based survey.

Diagnostics of asthma bronchiale and COPD at the doctors surgery

The ambition of the broadly created project was to ascertain the diagnostical accuracy of clinical symptoms and diagnostical instruments at the doctors surgery, to develop strategies for betterment of the diagnostic at suspition of asthma bronchiale/ COPD. Concerning this, in a

survey of the technical university Munich/ clinical centre on the right to the Isar, more than 1000 patients of doctors surgeries, pulmonary specialists, university hospitals and specialists-hospitals were included. Thereby a question about if the textbook knowledge, that is often generated in hospital environment, is actually conferrable to the doctors surgery, arose. These ailments are very common, but cause high expenses and are often underdiagnosed. The outcomes of this project have been achieved with data of 219 patients of 10 doctors surgeries and with 259 patients of a pulmonary specialists surgery; 253 of the university hospital Heidelberg and 300 patients of a specialists-hospital.

It could be displayed that diagnostical accuracies of clinical symptoms, when suspitious of asthma bronchiale/ COPD are not transferable from the hospital environment to the doctors surgery. Lately that shows, that the logic of the „primary care physicians laws of surgery" cannot be simply transcribed of the clinical textbooks. Especially in the field of diagnostic there is a high need of studies, to be able to understand the primary care physicians princliples better and to optimize the patients health care. Furthermore we arrived to the conclusion that, by optimal realization of the spirometriation, COPD can be diagnosed or precluded with high guaranty. Whereas asthma bronchiale can be diagnosed with spirometriation, but not precluded. If the spirometriation is inconspicuous, the patient should be transferred to a pulmonary specialist. Another achievement is that the peak-flow-variability is improper as a diagnostical method to preclude or diagnose astma bronchiale, if the spirometriation wasn´t helpful. With the NO-metriation a diagnostical principle is given with which at one subgroup an inclusion respectively exclusion would be possible. Two patients would have to be examined, to spare one of them from the bronchoprovocation. Admittedly this method is yet to expensive for a doctors surgery. With measuring results at the intermediate area (16ppb < NO < 46ppb) a transfer zu the pneumologist for performance of a bronchoprovocation would have to follow, to be able to make a secure diagnostic.

This successfully completed Project has been honoured with the german advancement award for general medicine in November 2009.

EvA (Emphysema versus Airways disease)

In the year 2007 the EU conceded with €3 mill the financing of the survey EvA, a research project, which deals with the chronic obstructive pulmonary disease (COPD). This project aggregates the clinical medicine, radiology and image analysis with genetic attributonal gene-expression analisys, lab diagnostics and bioinformatics. It differs from preceding surveys because of the distinction of the two subgroups of COPD (emphysem versus chronical bronchitis).

The consortium consists of 13 partners. 10 doctors, that recruit patients and collect samples and two partners, that examine the samples. The coordination is beeing carried out by the Helmholtz centre in Munich. The 13 partners are found in 9 european countries. For information about the members of the consortium and about the personnel, that take part at the EvA- project, please choose a country from the following list: France, Germany, Hungary, Italy, The Netherlands, Poland, Sweden, Swiss, Great Britain.

The concept to differ between emphysem and chronical bronchitis is new. This survey deals with an issue, that concerns doctors and scientists likewise, namely that many patients suffer from an illness, that can proceed variably. This aggravates as well the research as diagnosis and

therapy. The sub-groups will be parted from each other using a new CT-appraisal. It will also be examined, if smoking causes cyto- variances only at patients with a chronical bronchitis.

COPD patients and vonlunteers, that want to take place at the project, get a complete health check and pulmonary capacity check. To be able to differantiate between the two groups, a CT will be performed. Furthermore, for COPD patients as well as volunteers, there will be a bronchoscopy with a pulmonary lavation (BAL), to be able to get a sample. A blood sample is also taken.

Network of Competence "Asthma und chronical obstruktive pulmonary disease (COPD)"

Scientists of the Johannes Gutenberg University Mainz and the university medicin will investigate henceforth in scope of a nationwide network of competence a young, in Mainz developed method for diagnosis and devolution monitoring of the two pulmonary diseases with helium. The federal ministry for education and research (BMBF) allocates the Mainzer scientists therefore in the following three years (from august 2009) over 800.000 Euro. The total time of the BMBF-project shall be twelfe years.

With the illness-related networks of competence (KKN) the BMBF gives development funds for the progression and the expeansion of the illness related cross-linked research in germany. At the network of competence „asthma and chronical obstructive pulmonary disease (COPD)“ scientists of three research associations are involved.

The technology of Mainz with highly polarized helium-3 ist so to speak the golden standard for evaluation of the ventilation. Yet there is no comparable procedure, that can depict the lung so clearly without the radiation exposure of roentgen or CT. The patients breathe the inert gas helium, which serves as contrast medium and which is known from the diving medicine as well-tolerated. With the magnetic resonance tomography (MRT) the ventilation and blood-flow of the lung can be recorded precicely. The structure of this technique is deemed to be an outstanding accomplishment of the scientists of Mainz and the Johannes Gutenberg University is one of the global leading institutions on this field.

The new task for the cooperation partners for medicine and physics of Mainz now, is to clarify which further possibilities there are in the helium method. Can she be of help in the diagnostic? Can decisions about a therapy be made with this method? Can a differenciation between asthma and COPD be accomplished? There shall be so-called phantoms be build, so tat the real pictures of the lung can be understood easier. Support comes from the company MeVis in Bremen, a developer for software solutions for picturebased medicine. With the integration to a nationwide, long-term adjusted network of experts the research of pulmonary diseases with helium will, as hope the scientists, come of age and not only give a new insight into the lung, but perhaps also help to give new insights to the most important pulmonary diseases.

ILF – Institute for Pulmonary Research

This institue is a consolidation of the most importand associations and companionships on the field of pneumology. This institute has been founded in the year 2007 with the attempt to establish research promotion within the scope of patients supply. Thereby not only the hospitals and surgeries shall be noted, but rather the whole supply chain shall receive a

thorough examination. In the following subpoints the particular research activities shall be depicted.

Projekt Weaning (ventilatory weaning):

The project weaning of the supply research includes the weaning of the respirator with long term ventilated patients. This project has been started in june 2008 and in responsibility of ILF is being performed with close collaboration of the german compaionship for pneumology and ventilation-medicine e.V. The main goal is the development and provision of a specific database, to gather parameters about ventilatory weaning. For this purpose a first pilot phase of the weaning-units was started in november 2008 and amplification of the project on federal level started in january 2009. The duration of the project will be 10 years.

During this time relevant data about the structure, the processes and the outcome of the weaning of those clinical centres, that perform ventilatory weaning and take part at the project, will be collected. Beside the compilation and support of the data an important emphasis is on the scientific accompanyment and the evaluation of the data. Part of the data shall be natured in such way, that it can be a basis for structurated quality assurance in the future. Constantaneous they deliver information about the nationwide maintenance of weaning patients, because data about admittance and dismissal management is enclosed in the register.

The nationwide data is centrally brought together at the ILF within the scope of a database and beeing saved, used and processed in encrypted form.

Cognate subjected projects:

- KORA – Costs of the medical supply with smokers, ex-smokers and non-smokers in profile within the scope of the KORA survey.
- REMEO, of the Linde Group (transfer of long-term ventilationed COPD-4-patients from the intensive care unit into a rehab centre and finally back home)

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

BIBLIOGRAPHY.

Agency for Healthcare Research and Quality. 2010 *Quality Research for Quality Health Care. Available at:*<http://www.ahrq.gov/About/qr4qhc/qr4qhc-1.htm>.

Agency for Healthcare Research and Quality. 2010 *Technology Assessment. Available at:*<http://www.ahrq.gov/clinic/techix.htm>.

Agency for Healthcare Research and Quality. 2010 *What Is AHRQ? Available at:*<http://www.ahrq.gov/about/whatis.htm>.

APS Health Care & Agency of Human Services Office of Vermont Health Access. 2010 *Vermont Medicaid Chronic Care Initiative. Available at:*<http://www.vtccmp.com/>.

BOE. *Real Decreto 1030/2006, 15 septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización.Boletín oficial del Estado 16/9/2006.* http://www.boe.es/diario_boe/txt.php?id=BOE-A-2006-16212 .

Cherokee Health Systems. 2010 *Cherokee Health - Integrated Care. Available at:*<http://www.cherokeehealth.com/index.php?page=About-Us-Integrated-Care>.

COPDGene. 2010 *About COPDGene Study | COPDGene. Available at:*<http://www.copdgene.org/about-copdgene-study>.

COPDGene. 2010 *Home | COPDGene. Available at:*<http://www.copdgene.org/>.

COPDGene. 2010 *Study Design- Genetic Epidemiology of COPD. Available at:*<http://www.copdgene.org/study-design>.

Department of Health, United Kingdom. 2010 *Care Trust in Integrated Care. Available at:*<http://www.dh.gov.uk/en/Healthcare/IntegratedCare/Caretrusts/DH_361>.

Department of Health, United Kingdom. 2010 *Case Management. Available at:*<http://www.dh.gov.uk/en/Healthcare/Longtermconditions/casemanagement/DH_084250>.

Department of Health, United Kingdom. 2010 *Delayed discharges. Available at:*<http://www.dh.gov.uk/en/Healthcare/IntegratedCare/Delayeddischarges/index.htm>.

Department of Health, United Kingdom. 2010 *Integrated Care. Available at:*<http://www.dh.gov.uk/en/Healthcare/IntegratedCare/DH_091112>.

Department of Health, United Kingdom. 2010 *Long Term Conditions Model. Available at:*<http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Longtermconditionsmodel/DH_096409>.

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

Department of Health, United Kingdom. 2010 *Partnership Arrengements. Available at:*<http://www.dh.gov.uk/en/Healthcare/IntegratedCare/Healthact1999partnershiparrangements/index.htm>.

Department of Health, United Kingdom. 2010 *Prevention Package for older people. Available at:*<http://www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/Olderpeople/Preventionpackage/index.htm>.

Department of Health, United Kingdom. 2010 *Whole system demostrators. Available at:*<http://www.dh.gov.uk/en/Healthcare/Longtermconditions/wholesystemdemonstrators/index.htm>.

Docobo Ltd. Healthcare Solutions Provider. 2010 *Docobo's flagship telehealth service to enable monitoring, management and self care of patients at home with various long term conditions... Available at:*<http://www.docobo.co.uk/ArticlePage.aspx?articleId=6&topParentId=7>.

FAECAP Federación de Asociaciones de Enfermermería Comunitaria y Atención Primaria Available at: http://www.faecap.com/archivo/2004/12/01/la-consejeria-de-sanidad-de-murcia-colabora-con-la-oms-en-un-proyecto-para-implantar-una-nueva-cartera-de-servicios-en-2006-para-pacientes-diabeticos-y-de-epoc/.

Global University Network for Innovation-GUNI. 2010 *Proyecto e-Hospital de e-Learning. Available at:*<http://www.guni-rmies.net/observatory/bp.php?id=163>.

Improving Chronic Illness Care. 2010 *The Chronic Care Model. Available at:*<http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18>.

Institute of Health Science Education from Barts and The London School of Medicine and Dentistry. 2010 *Development, pilot and feasibility study for a chronic obstructive pulmonary disease (COPD) specific version of the Expert Patients Programme (EPP). Available at:*<http://www.ihse.qmul.ac.uk/chsgppc/bella/index.html>.

Instituto de Salud Carlos III. 2010 *Actividades de la Agencia de Evaluación de Tecnologías de la Salud. Available at:*<http://www.isciii.es/htdocs/investigacion/Agencia_actividades.jsp>.

Instituto de Salud Carlos III. 2010 *Agencia de Evaluación de Tecnologías Sanitarias. Available at:*<http://www.isciii.es/htdocs/investigacion/Agencia_quees.jsp>.

Instituto de Salud Carlos III. 2010 *Funciones de la Agencia de Evaluación de Tecnologías de la Salud. Available at:*<http://www.isciii.es/htdocs/investigacion/Agencia_funciones.jsp>.

Kao-Ping Chua. , 2006 *Overview of the U.S. Health Care System.* . AMSA Jack Rutledge Fellow 2005-2006 Association ed., , February 10, 2006.

Project partially funded by the European Commission
as part of the Ambient Assisted Living (AAL) Program

Ministerio de Sanidad y Política Social. 2009: *Estrategia En EPOC Del Sistema Nacional De Salud. Ministerio de Sanidad y Consumo. Centro de Publicaciones. Madrid.*

Ministerio de Sanidad y Política Social, Instituto de Información Sanitaria. , 2010 *National Health System of Spain.* http://www.msc.es/en/organizacion/sns/libroSNS.htm ed. Madrid: [consultado 5/12/2010].

National Health Service, United Kingdom. 2010 *Care Quality Commission (CQC). Available at:*<http://www.nhs.uk/NHSEngland/thenhs/healthregulators/Pages/carequalitycommission.aspx>.

National Health Service, United Kingdom. 2010 *Integrated Care Network. Available at:*<http://old.networks.nhs.uk/networks/page/744>.

National Health Service, United Kingdom. 2010 *NHS core principles. Available at:*<http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhscoreprinciples.aspx>.

National Health Service, United Kingdom. 2010 *NHS structure. Available at:*<http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhsstructure.aspx>.

National Health Service, United Kingdom. 2010 *Overview. Available at:*<http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx>.

National Institute for Health Research, United Kindgdom. 2010 *Home- National Institute for Health Research. Available at:*<http://www.nihr.ac.uk/Pages/default.aspx>.

NGUYEN, H.Q.; CARRIERI-KOHLMAN, V.; RANKIN, S.A.; SLAUGHTER, R. & STULBARG, M.S. 2003: Pilot Study of an Online Dyspnea Self-Management Program for COPD. *AMIA Annual Symposium Proceedings,* 951.

NGUYEN, H.Q.; GILL, D.P.; WOLPIN, S.; STEELE, B.G. & BENDITT, J.O. 2009: Pilot Study of a Cell Phone-Based Exercise Persistence Intervention Post-Rehabilitation for COPD . *International Journal of Chronic Obstructive Pulmonary Disease,* 4301-4313.

NHS East of England. 2010 *Fit for the Future: Local NHS funding. Available at:*<http://www.eoe.nhs.uk/news_archive.php?area_id=9&id=18>.

Nottingham National Health Service. 2010 *COPD - INFORCE. Available at:*<http://www.nottinghamcity.nhs.uk/-healthy-living-/copd-inforce.html>.

OPIMEC Observatorio de Prácticas Innovadoras en el Manejo de Enfermedades Crónicas Complejas. 2010 *The Indiana Chronic Disease Management Program. Available at:*<http://www.opimec.org/practicas/448/the-indiana-chronic-disease-management-program/>.

OPIMEC Observatorio de Prácticas Innovadoras en el Manejo de Enfermedades Crónicas Complejas. 2010 *Proyecto CHRONIC- Hospital Clínic de Barcelona. Available at:*<http://www.opimec.org/practicas/9/barcelona-proyecto-chronic/>.

Oxford Health Alliance. 2010 *Initiatives — Oxford Health Alliance. Available at:*<http://www.oxha.org/initiatives/initiatives>.

Scottish Centre for Telehealth. 2010 *Chronic Obstructive Pulmonary Disease (COPD) Remote Rehabilitation Classes via video link. Available at:*<http://www.sct.scot.nhs.uk/copdtayside.html>.

St. Thomas Hospital. 2010 *The COPD Project: 24/7 Action Line. Available at:*<http://www.copdproject.co.uk/24_7.htm>.

St. Thomas Hospital. 2010 *The COPD Project: better breathing for life. Available at:*<http://www.copdproject.co.uk/>.

St. Thomas Hospital. 2010 *Primary Care Guidance. Available at:*<http://www.copdproject.co.uk/primarycare_guidance.htm>.

Telemedicine and e-Health Information Service, United Kingdom. 2010 *Defence Technology for Health - Chronic Obstructive Pulmonary Disease (DTfH - COPD). Available at:*<http://www.teis.nhs.uk/jsp/search/activity.jsp?project=1243>.

The White House. 2010 *U.S. Health Reform. Available at:*<http://www.whitehouse.gov/issues/health-care>.

University of Birmingham, Health Service Management Centre. 2010 *NHS / Kaiser Permanente Programme. Available at:*<http://www.hsmc.bham.ac.uk/consult/permanente_programme.shtml>.

REFERENCES FROM GERMANY:

GENERAL INFORMATION ABOUT THE NATIONAL HEALTHCARE SYSTEM

1. Structure & specifics

- bpb Bundeszentrale für politische Bildung: Gesundheitspolitik: http://www.bpb.de/themen/X9C5R7,0,0,Gesundheitspolitik.html
- Bundesministerium für Gesundheit: Fragen und Antworten zur Vergütungsreform, 20.04.2009
- Bundesministerium für Gesundheit: http://www.bmg.bund.de
- Bundesversicherungsamt: So funktioniert der neue Risikostrukturausgleich im Gesundheitsfonds, 16.09.2008
- Diagnosis Related Groups: http://de.wikipedia.org/wiki/Diagnosis_Related_Groups
- KBV Kassenärztliche Bundesvereinigung: EBM 2009, auf dem Weg zur echten Gebührenordnung, 2009
- Knieps F, Leber C: Die Neuordnung der vertragsärztlichen Vergütung – Darstellung und Zielsetzung der gesetzlichen Regelungen, 2008

2. Options for the implementation of innovative care concepts

- Arbeitsgemeinschaft der Spitzenverbände der Krankenkassen: Leitfaden Prävention, 2008
- bpb Bundeszentrale für politische Bildung: Gesundheitspolitik: http://www.bpb.de/themen/X9C5R7,0,0,Gesundheitspolitik.html
- Bundesministerium für Gesundheit: http://www.bmg.bund.de
- Deutsche Gesellschaft für Integrierte Versorgung (DGIV), Bundesverband Managed Care (BMC): Positionspapier zur Anschubfinanzierung der Integrierten Versorgung in Deutschland, 2008
- Heuzeroth V: Realität in der Integrierten Versorgung – Fazit, in: Realität in der integrierten Versorgung – eine Zwischenbilanz, Hrsg.: wissenschaftlicher Beirat der TAUNUS BKK, 2007
- KBV Kassenärztliche Bundesvereinigung: Ärztliche Kooperationsformen im Überblick, 18.05.2009
- Strippel H, Handschuch M, Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e. V. (MDS): Präventionsbericht 2008 der gesetzlichen Krankenkassen, 2009

COPD AS A CHRONIC DISEASE OF THE PULMONARY SYSTEM

- Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin, http://www.degam.de/dokumente/aktuell_2009/Pressematerialien%202009.pdf (last visit 15.11.2009)
- Emphysema versus Airways disease, http://www.eva-copd.eu/ (last visit 15.11.2009)
- Helmholtz Zentrum München, http://www.helmholtz-muenchen.de/igm/projektepublikationen/index.html (last visit 15.11.2009)
- Institut für Lungenforschung e.V., http://www.lungenforschung.org/ (last visit 15.11.2009)
- Universität Mainz, http://www.uni-mainz.de/downloads/BMBF_KompNetz_BF_fin_02.pdf (last visit 06.08.2009)