FINANCIERINGSSYSTEMEN VAN ZIEKENHUISGENEESMIDDELEN: EEN BESCHRIJVENDE STUDIE VAN EEN AANTAL EUROPESE LANDEN EN CANADA

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Federaal Kenniscentrum voor de Gezondheidszorg
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Het Federaal Kenniscentrum voor de Gezondheidszorg

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Voorwoord

Als een eerste aanzet tot een rationeel gebruik van ziekenhuisgeneesmiddelen werd in 1997 een forfaitaire vergoeding ingevoerd voor het profylactisch gebruik van antibiotica bij heelkundige interventies. Antibioticaprofylaxie is de preventieve toediening van antibiotica om infectieuze postoperatieve complicaties te voorkomen. Voor alle andere geneesmiddelen geldt in België een vergoeding per verbruikt product. In 2002 werd door de toenmalige Minister van Sociale Zaken het voorstel gedaan om ook andere geneesmiddelen op een prospectieve manier - op basis van de case-mix (APR-DRG) - te vergoeden. Het voorstel had enkel betrekking op een limitatieve lijst van geneesmiddelen die bij heelkundige interventies worden toegediend. Over het ontwerp-KB werd herhaaldelijk een negatief advies uitgebracht om uiteenlopende redenen. Het voorstel voor een forfaitaire financiering was beperkt tot een aantal geneesmiddelen en had uitsluitend betrekking op patiënten die een chirurgische ingreep ondergaan.

Om een oordeelkundig advies over de forfaitaire vergoeding van ziekenhuisgeneesmiddelen als instrument voor het beheersen van de ziekenhuisuitgaven te kunnen formuleren aan Minister Demotte, werd recent door de Multipartite overlegstructuur voorgesteld dat het Federaal Kenniscentrum voor de Gezondheidszorg dringend een vergelijkende studie zou maken over de financiering van ziekenhuisgeneesmiddelen in een aantal omringende landen.

Dit rapport biedt een overzicht van de financieringssystemen van ziekenhuisgeneesmiddelen in Frankrijk, Duitsland, Zwitserland, Nederland, het Verenigd Koninkrijk en twee provincies in Canada (Ontario en Quebec). Bij de beschrijving van elk land wordt telkens ook uitgebreid ingegaan op de manier waarop de ziekenhuizen in het algemeen gefinancierd worden. In alle geselecteerde landen wordt bij de ziekenhuisfinanciering immers geen onderscheid gemaakt tussen de uitgaven aan geneesmiddelen en de andere uitgaven, met uitzondering van specifieke regelingen voor dure en/of innovatieve geneesmiddelen. Alle landen hebben heel recent grondige hervormingen in de financiering van ziekenhuizen doorgevoerd of zijn dit van plan te doen in de nabije toekomst. Een beschrijving van de oude én nieuwe systemen bood de mogelijkheid om, zonder expliciet de voor- en nadelen van de verschillende systemen te evalueren, toch impliciet de algemene tendens naar een financiering per case-mix als mogelijk instrument om de uitgaven te beheersen vast te stellen. Maar ook andere doelstellingen, naast een beheersen van de uitgaven, liggen aan de basis van meer pathologie-gerelateerde financieringssystemen.

België is een uniek land. Dat blijkt als conclusie uit deze beschrijvende studie over de stand van zaken in andere landen die het Kenniscentrum uitvoerde op vraag van de Multipartite overlegstructuur. Een belangrijke constante in de andere landen is de evolutie van een systeem met een globaal budget, meestal betaald per diem, naar een "all-in case-mix" financieringssysteem waarin ook de geneesmiddelen opgenomen zijn. De concrete invulling van "all-in" verschilt wel van land tot land. Een "all-in" systeem heeft als theoretisch voordeel dat de kans op een overschrijding van de gemiddelde kosten kleiner is dan wanneer een case-mix systeem slechts op een beperkt deel van de ziekenhuisactiviteit van toepassing is. Om te voorkomen dat voor dure geneesmiddelen het ziekenhuisbudget of de gemiddelde betaling per case ontoereikend wordt, hebben de meeste landen voorzien in een aparte financiering voor een beperkte lijst van dure geneesmiddelen.

Het onderzoeken van de voor- en nadelen van het huidige Belgische systeem voor de kwaliteit van zorgen en het doelmatig gebruik van de middelen van de ziekteverzekering maakte geen deel uit van deze (urgente) opdracht. Het KCE heeft geen specifieke beleidsaanbevelingen geformuleerd, vermits deze opdracht zijn oorsprong kende in de Multipartite tot wiens specifieke bevoegdheid het toekomt om hieromtrent een advies te geven aan de Minister. We hopen dat deze studie door de Multipartite als nuttig zal ervaren worden in het formuleren van haar advies aan de Minister over de financiering van geneesmiddelen in de Belgische ziekenhuizen.

Een speciaal woord van dank gaat naar Elias Mossialos van de London School of Economics[1] en naar de vele nationale experten in alle besproken landen die met veel kennis van zaken een belangrijke bijdrage leverden aan dit rapport.

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[1] Mossialos E, Mrazek M, Walley T. Regulating pharmaceuticals in Europe: striving for efficiency, equity, and quality. Maidenhead, Berkshire: Open University Press; 2004.

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Monsieur le Directeur,

Suite à ma demande d'avis concernant le financement forfaitaire des médicaments en milieu hospitalier, adressé à la Multipartite le 23 avril 2004, celle-ci s'est penchée sur le sujet et souhaiterait disposer de la part du Centre Fédéral d'Expertise des Soins de Santé d'une étude comparative entre pays voisins en matière de financement des produits pharmaceutiques en milieu hospitalier.

Cette étude devrait ainsi permettre de fonder l'avis de la multipartite à partir de l'expérience étrangère en donnant un aperçu des différents systèmes de financement des médicaments en milieu hospitalier.

Je voudrais insister sur le caractère prioritaire de cette mission afin que la multipartite puisse rapidement poursuivre ses travaux en la matière. En conséquence, je vous remercie de traiter cette demande dans le cadre de la procédure d'urgence et de veiller à me communiquer les résultats dans un délais de trois mois.

Je vous prie d'agréer, Monsieur le Directeur, l'assurance de mes meilleurs sentiments.

Rudy Demotte

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Samenvatting

Inleiding

In België worden de ziekenhuisgeneesmiddelen vergoed per verbruikt product. In 1997 werd hierop een uitzondering gemaakt door voor het profylactisch gebruik van antibiotica bij heelkundige interventies een forfaitaire vergoeding in te voeren. De forfaits variëren in functie van de heelkundige interventie en zijn gebaseerd op klinische richtlijnen. Sedertdien werden verschillende voorstellen geformuleerd om ook andere geneesmiddelen die bij heelkundige interventies worden toegediend, op een prospectieve manier te financieren.

In de bestudeerde landen bestaan verschillende financieringssystemen die een uiteenlopend effect hebben op het gedrag van de zorgverlener en in verschillende mate bijdragen tot de efficiëntie, kwaliteit en toegankelijkheid van de gezondheidszorg. Daarom geven we eerst een typologie van financieringssystemen van ziekenhuizen met hun verwachte effecten. De systemen kunnen op basis van verschillende criteria ingedeeld worden. We maken een onderscheid tussen de volgende dimensies: vaste versus variabele financiering, retrospectieve versus prospectieve financiering en volgens de betalingseenheid.

Daarna volgt een overzicht van de financieringssystemen van ziekenhuisgeneesmiddelen in een aantal omliggende landen en Canada. Bij de beschrijving van elk land wordt uitgebreid ingegaan op de manier waarop ziekenhuizen gefinancierd worden. In alle geselecteerde landen wordt bij de ziekenhuisfinanciering immers geen onderscheid gemaakt tussen de uitgaven aan geneesmiddelen en de andere uitgaven. Alleen voor dure en/of innovatieve geneesmiddelen zijn specifieke regelingen voorzien. Omdat alle landen heel recent grondige hervormingen in de financiering van ziekenhuizen hebben doorgevoerd of dit van plan zijn te doen in de nabije toekomst, beschrijven we telkens het oude én nieuwe systeem.

Frankrijk

Momenteel worden publieke ziekenhuizen in Frankrijk gefinancierd door middel van een globaal budget waarin de honoraria en de ziekenhuisgeneesmiddelen zijn inbegrepen. Voor bepaalde dure en innoverende geneesmiddelen worden soms nationale kredieten door het Ministerie van Gezondheid toegekend. Private ziekenhuizen worden echter gefinancierd door een verpleegdagprijs voor het logement en de verpleging, een dagelijks forfait voor geneesmiddelen en diverse forfaits voor de technische omgeving nodig voor het uitvoeren van bepaalde procedures. De honoraria worden apart vergoed per prestatie.

Volgens de recente hervormingen zullen de publieke en private ziekenhuizen vanaf december 2004 geleidelijk aan evolueren naar een prospectieve financiering gebaseerd op de feitelijke pathologiestructuur van elk ziekenhuis. Het classificatiesysteem om de verblijven te groeperen is een Franse variant van het Amerikaanse DRG-systeem.

Het is de bedoeling om ziekenhuisgeneesmiddelen op te nemen in de forfaits per pathologie. Voor een beperkte lijst van dure en innovatieve geneesmiddelen zal echter een aparte financiering voorzien worden. Om op deze lijst opgenomen te worden moet het geneesmiddel duur zijn én moet er een grote variatie in voorschrijven bestaan tussen de pathologiegroepen.

Duitsland

Vóór 1993 werden Duitse ziekenhuizen gefinancierd volgens het principe van de volledige kostendekking. De ziekenfondsen stonden via allerlei aanpassingen in voor het verschil tussen het gerealiseerde aantal verpleegdagen en het geraamde aantal dagen waardoor de feitelijke betaling in functie van het aantal gerealiseerde verpleegdagen

gebeurde, ongeacht of die retrospectief of prospectief berekend werden. Door de hervormingen die sinds 1993 zijn doorgevoerd, werden de flexibele budgetten vervangen door vaste budgetten en is het principe van de volledige kostendekking afgeschaft. Het ziekenhuisbudget bestond voortaan uit vier verschillende componenten: basisverpleegdagprijzen voor niet-medische kosten, afdelingsverpleegdagprijzen voor medische kosten, vergoedingen per case voor een limitatieve lijst van behandelingen en vergoedingen per procedure voor een lijst van geselecteerde procedures. Elk ziekenhuis moest hierbij onderhandelen met de lokale ziekenfondsen over het volume en de hoogte van de per diem bedragen. De medisch specialisten ontvingen een salaris dat deel uitmaakte van het ziekenhuisbudget.

Vanaf 2004 is een nieuw financieringssysteem op basis van een vergoeding per case ingevoerd, gebaseerd op het Australische Refined DRG-systeem. Hierbij is een overgangsfase van vijf jaar voorzien om over te stappen van een prijs per DRG die gebaseerd is op de kostenstructuur van elk ziekenhuis naar een prijs op het niveau van de Länder.

In het oude systeem dekten de afdelingsverpleegdagprijzen de kosten van geneesmiddelen. In het nieuwe systeem worden de kosten van geneesmiddelen in principe meegenomen bij de berekening van het relatieve gewicht van elke DRG. Voor een welomschreven lijst van dure geneesmiddelen krijgen de ziekenhuizen extra financiering. Deze extra betaling kan zowel specifiek voor een bepaald ziekenhuis als identiek voor alle Duitse ziekenhuizen zijn.

Zwitserland

In het huidige systeem in Zwitserland bepalen akkoorden tussen verzekeraars en ziekenhuizen op het niveau van het kanton de financiering van ziekenhuizen. Het systeem verschilt in belangrijke mate volgens het kanton, het ziekenhuis en het type kamer. Over het algemeen worden de werkingskosten van publieke ziekenhuizen gefinancierd op basis van een forfaitsysteem (verpleegdagprijs, forfait per verblijf in een welbepaalde afdeling of een forfait per AP-DRG), terwijl een betaling per prestatie wordt toegepast in private ziekenhuizen of in private kamers van publieke ziekenhuizen. Tussen nu en 2006 zullen de publieke ziekenhuizen van 14 kantons een financieringssysteem per AP-DRG invoeren.

Wanneer een ziekenhuis per prestatie betaald wordt, worden de geneesmiddelen per stuk gefinancierd. Bij een betaling op basis van forfaits zijn de ziekenhuisgeneesmiddelen inbegrepen. Niettemin laat de Zwitserse wetgeving de mogelijkheid om "diagnostische prestaties of speciale technieken" apart te financieren. Op die manier kan het gebeuren dat bepaalde dure geneesmiddelen niet in de forfaits zijn opgenomen.

De federale overheid in Zwitserland heeft recent een hervorming van de federale wet op de ziekteverzekering voorgesteld met de bedoeling een prospectieve pathologiefinanciering voor ziekenhuizen in te voeren. Hierbij zou het classificatiesysteem van de pathologieën op federaal niveau bepaald worden, terwijl de forfaits per pathologie kunnen verschillen. De ziekenhuisgeneesmiddelen zouden in de forfaits per pathologie opgenomen worden, maar de problematiek van de dure geneesmiddelen wordt op dit moment nog onderzocht.

Nederland

In de afgelopen decennia heeft Nederland verschillende systemen gekend voor de financiering van de ziekenhuizen. In 1983 werd het open-eind systeem gebaseerd op outputfinanciering vervangen door een gesloten-eind systeem dat zich op micro-niveau vertaalde in de invoering van een budget. Gedurende de eerste jaren was dit in de vorm van historische budgetten, maar in 1988 werd de functiegerichte budgettering (FB) ingevoerd, waarbij er een grotere aansluiting tussen de ziekenhuisfuncties en de beschikbaar gestelde middelen werd nagestreefd. In de FB-systematiek bestond het ziekenhuisbudget uit verschillende parameters die gerelateerd zijn tot vaste, semi-vaste en variabele kosten. Hoewel de tarieven voor deze parameters op prospectieve wijze

bepaald werden, konden de werkelijk gemaakte kosten hiervan afwijken waardoor het FB-systeem meer als een open-eind systeem beschouwd moet worden. Gedurende de hele periode werden de ziekenhuizen hoofdzakelijk per verpleegdag bekostigd. De financiering van de medisch specialisten evolueerde van een betaling per prestatie naar een lump-sum financiering.

Vanaf 1 januari 2005 wordt een nieuw financieringssysteem ingevoerd dat de functiegerichte budgettering van ziekenhuizen en de lump-sum financiering van medisch specialisten vervangt. Dit systeem is gebaseerd op de Diagnose Behandeling Combinatie (DBC). Een DBC is het geheel van activiteiten en verrichtingen van een ziekenhuis en medisch specialist voortvloeiend uit de zorgvraag waarmee een patiënt de specialist in het ziekenhuis consulteert.

Het gaat zowel over klinische en poliklinische behandelingen als behandelingen in een dagkliniek. De prijs van een DBC voor een bepaald ziekenhuis wordt berekend aan de hand van de kosten van dat ziekenhuis en bevat een vergoeding zowel voor het ziekenhuis als voor de medisch specialist. De invoering van het nieuwe systeem verloopt in verschillende fasen. Na een lange periode van inzamelen van gegevens en vastleggen van de behandelingen voor elke DBC, kunnen ziekenhuizen vanaf 1 januari 2005 voor 10% van het ziekenhuisbudget (segment B) vrij onderhandelden en kunnen ze afspraken maken met de verzekeraars over het aantal DBCs, de prijs en de kwaliteit. Voor de overige 90% van het ziekenhuisbudget (segment A) is een nationale prijs per DBC vastgelegd en blijft het huidige FB-systeem van kracht. Vanaf 2006 zal het deel van het budget waarvoor vrije onderhandelingen mogelijk zijn, toenemen.

In het FB-systeem werden de geneesmiddelen gefinancierd vanuit het globaal ziekenhuisbudget. Vanaf 2005 bepalen de kosten van geneesmiddelen mee de prijs van een DBC, zowel de nationale prijs in segment A als de onderhandelde prijs in segment B. In 2002 werd een aparte regeling voor een limitatieve lijst van dure geneesmiddelen ingevoerd waardoor ziekenhuizen via onderhandelingen met de verzekeraars tot 75% van de reële kosten extra vergoed konden krijgen. In de nieuwe regeling vallen de dure geneesmiddelen onder segment A.

Verenigd Koninkrijk

De National Health Service (NHS) van het Verenigd Koninkrijk heeft verschillende hervormingen ondergaan sedert haar oprichting in 1948. De hervorming met de belangrijkste implicaties voor de ziekenhuissector was de creatie van de interne markt met de splitsing van de functie van zorgaanbieder en zorginkoper en de oprichting van de NHS Trusts (1991). Ziekenhuizen contracteren met verschillende zorginkopers en kunnen volgende contracten afsluiten: blokcontracten, kosten- en volumecontracten en kosten per geval contracten.

De medisch specialisten worden een salaris uitbetaald, dat ze echter kunnen aanvullen met een private praktijk.

Vooral om de toenemende wachtlijsten en wachttijden in te perken, werden vanaf 2000 grondige hervormingen doorgevoerd in de manier waarop de NHS-middelen ingezet worden. Deze hervormingen, die gepaard gingen met een substantiële toename van NHS-budget, houden in dat ziekenhuizen betaald worden volgens de verleende activiteit (“payment by results”) op basis van een eigen variant op de Amerikaanse DRGs, met name de Health Resource Groups (HRGs). Het nieuwe systeem zal in verschillende stappen ingevoerd worden. In een eerste fase kunnen de ziekenhuizen voor een beperkt aantal chirurgische interventies met zorginkopers onderhandelen over volume en prijs op basis van de HRGs. Vanaf 2005/2006 zal een nationaal tarief gelden voor alle intramurale, ambulante en spoeddiensten.

In het oude systeem werden de ziekenhuisgeneesmiddelen vergoed via de contracten die de ziekenhuizen afsloten met de zorginkopers. In het HRG-systeem maken de kosten van de geneesmiddelen deel uit van het nationaal tarief per HRG. Voor dure geneesmiddelen wordt in een aparte financiering voorzien.

Canada – Ontario

Het merendeel van de ziekenhuizen in Ontario is publiek. Ze worden gefinancierd door middel van een globaal budget waarin de uitgaven voor geneesmiddelen inbegrepen zijn. De honoraria worden apart gefinancierd, behalve uitzonderingen. De ziekenhuizen ontvangen voor een lijst van 14 antikanker geneesmiddelen speciale kredieten indien deze geneesmiddelen worden voorgeschreven op basis van specifieke richtlijnen.

Om het totale ziekenhuisbudget van Ontario over de ziekenhuizen te verdelen, werd een verdeelformule ontwikkeld die het budget van elk ziekenhuis koppelt aan haar activiteiten en haar doeltreffendheid. De formule houdt rekening met het verwachte zorgvolume als functie van de lokale bevolkingskarakteristieken en met de verwachte kosten. De verwachte kost wordt berekend per pathologiegroep volgens een classificatiesysteem specifiek voor Ontario. Ziekenhuizen met een werkelijke kost lager dan de verwachte kost worden in principe beloond bij de verdeling van het budget.

De vereniging van ziekenhuizen in Ontario heeft samen met de Senaatscommissie verantwoordelijk voor sociale zaken een hervorming van het financieringssysteem van ziekenhuizen voorgesteld waarbij zou overgestapt worden naar een prospectieve pathologiefinanciering volgens het classificatiesysteem momenteel in voege in Ontario. De financiering van ziekenhuisgeneesmiddelen zou in principe inbegrepen zijn in de forfaits per pathologiegroep, met uitzondering van enkele antikanker geneesmiddelen waarvoor de speciale kredieten van kracht blijven.

Canada – Quebec

De publieke ziekenhuizen in Quebec worden gefinancierd op basis van een globaal budget met inbegrip van alle ziekenhuisgeneesmiddelen. Honoraria zijn echter niet in het globaal budget opgenomen maar worden per prestatie betaald door de “Régie de l’assurance-maladie” van Quebec. Private ziekenhuizen staan zelf in voor hun financiering.

Het Ministerie van gezondheid heeft in juni 2000 een commissie opgedragen om het financieringssysteem van ziekenhuizen te herbekijken. Het voorstel van de commissie was om de financiering te laten afhangen van het verwachte volume en de verwachte kost per pathologiegroep volgens het classificatiesysteem van de AP-DRG. Bij de berekening van de verwachte kost zijn ook de ziekenhuisgeneesmiddelen opgenomen. Uitzonderingen worden niet overwogen.

Besluit

Het merendeel van de bestudeerde landen evolueert, weliswaar tegen een uiteenlopende snelheid, in de richting van een prospectieve ziekenhuisfinanciering op basis van de pathologiestructuur. Ze gebruiken daartoe een aantal soortgelijke registratiesystemen: AP-DRG (Zwitserland, Quebec), AR-DRG (Duitsland), HRG (Verenigd Koninkrijk), DBC (Nederland), GHS (Frankrijk) en CMG (Ontario). De overgang verloopt in het algemeen in verschillende fases, meestal verspreid over meerdere jaren.

De forfaits die per type pathologie berekend worden, zijn globale forfaits waarin de ziekenhuisgeneesmiddelen en in de meeste gevallen ook de honoraria inbegrepen zijn. Nederland en ook het Verenigd Koninkrijk gaan nog een stap verder en nemen ook ambulante ziekenhuiszorg op in de forfaits.

In de meeste landen wordt rekening gehouden met de problematiek van dure geneesmiddelen, voornamelijk geneesmiddelen in het domein hematologie/oncologie en immunomodulerende geneesmiddelen. Een welomschreven lijst wordt op een andere wijze gefinancierd. Deze lijst met dure geneesmiddelen is opgemaakt aan de hand van criteria die van land tot land verschillen: geneesmiddelen die gemiddeld genomen duidelijk duurder zijn (Frankrijk, Nederland), variatie in kosten binnen eenzelfde

pathologiegroep (Frankrijk), volgens voorschrijfrichtlijnen (Canada-Ontario). Ook de problematiek van outliers krijgt in het merendeel van de landen heel wat aandacht.

België is in vergelijking met de bestudeerde landen het enige land waar de financiering per pathologie op een gefragmenteerde manier gebeurt. Een "all-in" systeem zoals in de meeste andere landen heeft als voordeel dat de kans op een overschrijding van de gemiddelde kosten kleiner is omdat er substitutie kan optreden tussen de verschillende kostencomponenten en tussen patiënten met verschillende zorgzwaarte en de eraan verbonden kosten. Bij een case-mix systeem dat slechts op een beperkt deel van de ziekenhuisactiviteit van toepassing is, zoals het recente voorstel dat betrekking heeft op een limitatieve lijst van ziekenhuisgeneesmiddelen die bij heelkundige interventies worden toegediend, bestaat deze mogelijkheid minder. Voorwaarde voor dergelijke "all-in" systemen is wel dat de globale financiering volstaat om te voorzien in een verantwoorde zorg.

Scientific summary

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1. INTRODUCTION

1.1. BACKGROUND

In a first attempt to control hospital drugs costs, a prospective financing system was introduced in 1997 in Belgium for the prophylactic use of antibiotics in surgical operations. The calculation of these lump sums is based on clinical guidelines.

Other types of hospital drugs are reimbursed on a fee-for-service basis in Belgium. A proposal has been made in 2002 by the Social Affairs Minister to set up a prospective financing system, based on case-mix (APR-DRGs[a]), for the reimbursement of a wider range of hospital drugs used in surgical operations.

In order to give a well-motivated advice on a renewed proposal of the current Minister of Social Affairs and Public Health, the "Structure Multipartite-Multipartite Overlegstructuur" asked the Belgian Health Care Knowledge Centre (KCE) to make a review of the hospital drugs financing systems used in neighbouring countries (Letter of the Minister of Social Affairs and Public Health, on August 12, 2004, see page iii).

1.2. METHODOLOGY

After a general presentation of a typology of existing hospital financing systems, this report describes the situation encountered in six countries: France, Germany, Switzerland, The Netherlands, the United Kingdom and Canada (Ontario and Quebec)[b]. As the request by the Multipartite and the Minister did not specify the countries of interest, the selection of the countries analysed in this report was made on the basis of their geographical proximity and also in order to offer a diversified range of hospital financing systems (systems in different stages of transition, systems comparable to the Belgian system or different).

As the financing of hospital drugs is closely linked to the system of hospital reimbursement, we first describe shortly the current hospital financing system for each country. Since reforms have been implemented recently or are planned in the close future in nearly every country, we also describe each future hospital financing system. In the next sections, we give details on the financing of hospital drugs, with an emphasis on some exceptions in these systems, such as certain expensive drugs.

Finally, we conclude the report with a review of the main characteristics of the various systems.

Information was collected from governmental agencies, hospital, medical and pharmaceutical associations, and health insurer funds through literature searches, websites visits and personal contacts. For every country, a national expert was contacted in order to validate each national section of the report. The full draft of the report was also reviewed by an internationally recognized expert in health financing systems (see acknowledgements below).

[a] APR-DRGs: All Patient Refined Diagnosis Related Groups.

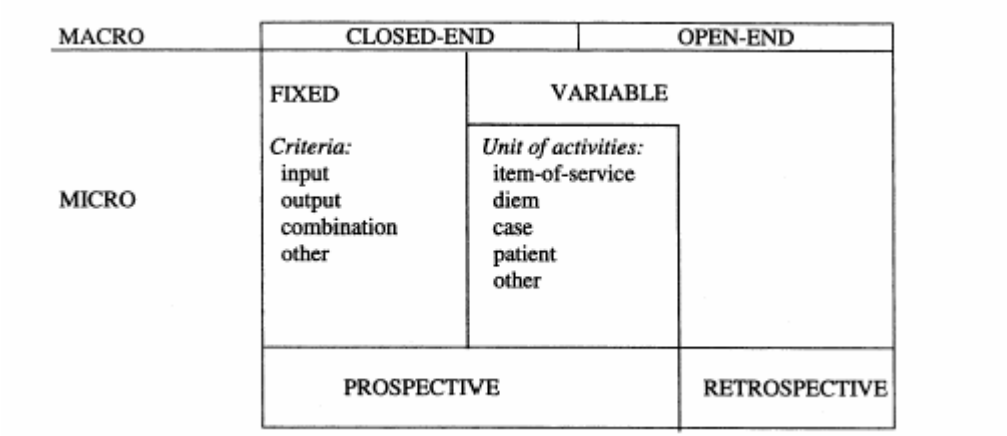
[b] Kesteloot et al. (2000) give an extensive description of health care provider payment systems in six European countries (the Netherlands, Germany, the UK, Sweden, France and Switzerland). They also analyse how these systems can influence provider behavior. Kesteloot K, De Graeve A, Jegers M et al. Financieringsmodellen van ziekenhuis-en transmurale zorg, voor toepassing in het vernieuwd Vlaamse gezondheidsbeleid. Ministerie van de Vlaamse Gemeenschap; December 2000. PBO97/46/37.

2. TYPOLOGY OF FINANCING SYSTEMS

The financing of hospital drugs is closely linked to and most of the time included in the system of hospital reimbursement. Therefore, we start with a description of payment mechanisms for hospitals.

We limit the description to the most frequently applied reimbursement systems. However, in reality, these systems are very often combined instead of using only one payment method. A classification of different types of hospital reimbursement systems can be addressed along different dimensions. The typology we present here (Figure 1) is based on Jegers[1,a]. They provide a framework to classify reimbursement systems according to the degree to which the systems influence provider behaviour and contribute to the quality, efficiency and accessibility of the health care system.

Figure 1: Typology of hospital reimbursement systems



Source: Jegers[1]

The basic dimensions of the typology are (1) fixed versus variable payments, (2) retrospective versus prospective payments and (3) unit of reimbursement.

1. Fixed versus variable payments

The dimension fixed versus variable payment refers to the relation between reimbursements to the hospital and provision of care services. In a fixed system payments do not depend on the provided activities. In a variable payment system reimbursement is activity-based.

Moreover, the distinction between fixed and variable systems can be made at the micro-level (hospital) as well as at the macro-level (all or group of hospitals). The macro-level is the relevant level for the payers of the system (government, insurers…) and the micro-level for the hospital management.

In a variable reimbursement system the hospital is paid according to its activities. Extra production of care will lead to extra payments. Because of this link between the hospital's income and its production, it is expected that hospitals have a strong incentive to increase production in a variable reimbursement system, particularly when the marginal income is relatively large compared to the marginal cost. In a fixed system extra production is not reimbursed. The hospital receives an ex-ante determined lump-sum, and when actual production exceeds the ex-ante determined volume, hospitals are not remunerated. Consequently, with lump-sum payments hospitals are expected to reduce marginal costs since marginal income is zero. This can be done by innovating in cost reducing technologies or by the use of lower cost alternative treatments. When this is not possible, the system may create incentives for preferred risk selection or quality skimping. Hospitals may be tempted to under-provide services to certain

[a] We focus on reimbursement systems that are relevant for hospitals.

patient groups or even to avoid high-cost patients. This behaviour has definite implications for the accessibility of high-need patients.

In general, the different reimbursement schemes can be seen as a continuum from variable to fixed systems. On the same continuum – from more variable to more fixed schemes - the following units of reimbursement can be considered: cost reimbursement, fee-for-service, per diem, case-based and per patient (capitation). In reality the incentive effects of fixed and variable reimbursement systems depend to a large extent on the fraction of the financial risk the hospital bears.

At the macro-level the distinction between fixed and variable boils down to the distinction between closed-end and open-end systems. In a closed-end system policymakers decide on the global budget to be spent during a certain period. Since closed-end budgeting establishes a fixed level of spending, it can be a useful instrument for cost-containment. In an open-end system there are no budget limits.

The real economic behaviour of hospitals depends on the financing schemes at both levels. For cost-containment purposes, it can be expected that a combination of a variable system at the micro-level and a closed-end macro-system gives the best results. Moreover, since extra production is financed per unit of production, it is a better guarantee for quality and accessibility provided that the macro budget is determined at a sufficient level.

2. Prospective versus retrospective payments

Very often the distinction between fixed/variable payments is made equal to the distinction between prospective/retrospective payments. However, there are essential differences. The dimension prospective/retrospective relates to the possible link between hospital reimbursement and hospital expenditures while the dimension fixed/variable links the hospital reimbursement to its production. Although costs and activities are closely related, they are not identical.

In fully retrospective systems the hospital's costs are fully covered whereas the hospitals get a fixed price in prospective systems. Retrospective reimbursement means that the payer reimburses all expenditures incurred on patients over the previous period. The hospital has no risk sharing and hence no incentive to produce efficiently. In a prospective system payment rates are set ex-ante as a fixed price which makes the hospital bear the total risk of the hospital expenditures.

What is the relation between the dimension fixed/variable and the dimension prospective/retrospective? A prospective system can be either fixed or variable, but a fully retrospective system is always variable. Fully fixed systems are always prospective, but variable systems can be prospective or retrospective depending on the relation between the reimbursements and the real costs.

3. Unit of reimbursement

Another way of classifying hospital reimbursement systems is according to the unit of reimbursement. On the continuum from variable to fixed payment systems, the following key types can be distinguished:

Fee-for-service payment

In a payment per item-of-service system hospitals are paid according to individual services provided. The price of each item is known ex-ante.

At the micro-level this system is to a large extent a variable system. Since the price per unit is fixed, it can be classified as a prospective system.

Payment per patient-day (per diem)

The per diem system is largely a variable system since an increased length of stay results in increased payments. The per diem price can be paid retrospectively (real costs are used to calculate the per diem) or prospectively (the price is fixed ex-ante independent of real costs).

Payment per case

In this system fees are set, most often in a prospective way, according to diagnosed medical conditions and standardised treatment costs. The best-known system to classify cases is the Diagnostic Related Groups System (DRG-system). The payment per case is a payment per hospital stay, irrespective of the real costs of the hospital or the length of stay but generally based on the average costs of a group of hopsitals.

Payment per patient[b]

In a capitation system the hospital is paid a periodic (mostly annual) lump-sum per patient.

Payment per period

Hospitals are paid a lump-sum for the treatment of patients in a given period. This system is by definition fixed, both at the micro- and macro-level.

The size of the hospital budget can be determined by input- or output-related measures. Input-related measures can be the number of types of beds which determine the capacity of a hospital. Typical output measures are patient-days, cases, admissions…

References

1. Jegers M, Kesteloot K, De Graeve D, Gilles W. A typology for provider payment systems in health care. Health Policy. 2002; 60: 255-273.

[b] This payment system is more relevant for general practitioners than for hospitals. Some HMOs in the US are paid per patient.

3. COUNTRIES DESCRIPTION

In this chapter we describe the financing system of hospitals and hospital drugs of six countries: France, Germany, Switzerland, The Netherlands, the United Kingdom and Canada. As health insurance and the administration, delivery and funding of health care services in Canada are not the responsibilities of the federal government but differ amongst provinces or territories, we have focused on two provinces: Ontario and Quebec.

3.1. FRANCE

French hospitals are financed differently according to the type of ownership. Public hospitals are financed on a global budget basis and private hospitals are reimbursed a fixed amount for each budget line item ("line-by-line funding") and a per diem rate. However, the financing scheme will change dramatically from December 2004 onwards. At that moment, both private and public hospitals will move to a prospective payment system based on case-mix.

We first describe the current hospital financing system. Then we summarize the main characteristics of the future reimbursement method. In the next sections, we explain the reimbursement of hospital drugs, with an emphasis on some exceptions.

3.1.1. Current hospital financing system

On a yearly basis, the Parliament approves a national ceiling for health insurance expenditure ("Objectif National de Dépenses d'Assurance Maladie" – ONDAM) for the following year. The ONDAM is usually determined by applying a growth factor to the previous year expenses. Once the global ceiling has been defined, the government splits it into four sub-groups:

- health care in private practice;
- health care in public hospitals;
- health care in private for-profit hospitals (except medical fees which are included in the first part); and
- social care (mainly the cost of institutions and services for elderly and disabled people)[1].

Currently the hospital financing system depends on the type of hospital ownership.

Public and private non-profit hospitals

These hospitals have global budgets. They are defined through a top-down procedure.

A national budget ("Dotation Globale de Financement") is determined by the Ministry of Health. It is then divided between regions, in order to reduce regional disparities[2]. The methodology to split the budget between the regions is based on:

- a theoretical volume of hospital stays, calculated with national occupancy rates applied to the regional demographic structure;
- a comparative mortality index;
- the patient flow between regions; and
- the regional hospital productivity which is measured by an indicator known as the "Indice Synthétique d'Activité" – ISA point. The regional value of an ISA point is calculated by dividing the total regional budget by the volume of activity weighted by the relative cost of each activity according to a national scale[a]. If the regional value of the ISA point is higher than the average, the region is considered to be less productive. This is taken into account when setting its budget[1].

[a] This system uses a categorization ("Groupe Homogènes de Malades" – GHM) similar to the diagnostic-related groups (DRG) used in the United States.

Once the regional budget has been decided, the Regional Hospital Agencies ("Agence Régionale d'Hospitalisation" - ARH) distribute it among hospitals taking into account mainly historical allocations. Some adjustments can be considered on the basis of specific targets in regional hospital planning and on the basis of hospital productivity (value of the ISA point).

Private for-profit hospitals

Each year, a national quantified target ("Objectif Quantifié National" - OQN) is negotiated between the state and the private for-profit hospitals. They set up a target budget for private for-profit hospitals. The OQN includes several tariffs.

If current expenses exceed the target at the national level, tariffs are lowered; if expenses are below the target, tariffs are increased.

The national agreement defines:

- the average national increase in tariffs;
- the average increase in each region (to reduce regional disparities); and
- the range of possible variations within regions.

At regional level, agreements are concluded between ARH and private for-profit hospitals in order to define rules for setting tariffs.

These rules take into account regional priorities, objectives for regional hospital planning and hospitals productivity (ISA points)[1,3].

The OQN does not include medical, dentist and biologist fees[b] but includes[1]:

- a per diem rate covering all accommodation expenses, nursing expenses and routine care of patients with overnight stays; the rate is set by discipline (medicine, surgery, obstetrics, etc.);
- an amount fixed at national level covering ambulatory surgery or treatment;
- an amount fixed at national level covering the use of minor supplies in the context of procedures carried out on an outpatient basis;
- a tariff for technical facilities needed for carrying out a procedure; this tariff is defined on the basis of a schedule which is strictly proportional to the fee schedule of doctors; and
- a per diem rate covering the consumption of drugs.

All tariffs are prospectively negotiated. With the exceptions indicated above, they vary between regions and hospitals.

Problems with the current system[4]

With the system of "Dotation Globale de Financement" for public and non-profit hospitals, there is little relation between the level of hospital activity or productivity and the level of hospital financing. Therefore it provides little incentives for efficiency. This could lead to recurrent over-financing or rationing. Hospitals with a decreasing activity can be over-financed and hospitals with an increasing activity can be penalised.

The reimbursement system of for-profit hospitals is based on the hospital activity, but tariffs are set on the basis of contracts and do not always reflect the real costs of activities. Therefore some activities can be under-financed and some over-financed. Some hospitals could then specialize in activities which are not adapted to patient needs.

The difference of financing between the public and the private sector generates inequalities in incomes and in care supply.

[b] These fees are included in the ONDAM "health care in private practice" sub-group.

3.1.2. Future hospital payment system

Beginning in December 2004, both public and private hospitals will move to a prospective payment system based on case-mix.

According to an act passed in 1991, public and private hospitals were required to evaluate their operation. For hospital stays involving medical, surgical and obstetric procedures, this evaluation is based on the production of a Standard Discharge Summary ("Résumé Standard de Sortie" - RSS) for each hospital stay. The RSS contains information on the nature of the treatment, on the nature of the examinations carried out during the patient's stay, on the diagnosis that led to the hospital admission and on the associated diagnoses or possible complications. The RSS is then integrated into one of 512 'patient groupings' ("Groupe Homogène de Malades"- GHM) used for classification of hospital stays. This classification is adapted from the US DRG-classification system[1].

A national baseline for costs per stay has been built up from a sample of hospitals producing a total cost evaluation of each stay. For each GHM, the median cost of all stays in the sample is taken as a reference point.

This median cost is used in the new prospective payment system to determine a lump sum for each GHS ("Groupe Homogène de Séjour"). Most of the time, a GHS corresponds exactly to a GHM.

This lump sum covers nursing care, accommodation and infrastructure for hospitalized patients, day-case treatments, hospital drugs and capital investment costs. For public and non for-profit hospitals, it also covers medical and technical acts (except consultations). Medical fees in private for-profit hospitals are not included in the lump sums and are reimbursed on a fee-for-service basis.

Each stay in classic hospitalisation or day-case treatment in medicine, surgery or obstetric is affected by the prospective payment system.

Outliers [5]

Some stays can be considered as outliers because their length of stay is below or above the GHS average length of stay. For each GHS, lower and upper limits will be calculated (the exact methodology is currently not yet elaborated). If length of stay is lower than the lower limit, half of the lump sum will be paid for the stay. If length of stay is higher than the upper limit, each day after the upper limit will be financed at 75%. Financing of the stay will then be:

$$\text{GHS lump sum} + \left(0.75 \times \frac{\text{GHS lump sum}}{\text{GHS average length of stay}} \times (\text{length of stay - upper limit}) \right)$$

Transition between the current and the new system[5]

The transition from the current system to the new one will be progressive and will end in 2014 at the latest. For private for-profit hospitals, a transition coefficient will be applied to lump sums in order to limit an eventual decrease in incomes. Public and private non-profit hospitals will receive annual complementary lump sums ("Dotation Annuelle Complémentaire") for the same reason.

3.1.3. Current hospital drugs financing system

Public and private non-profit hospitals

In principle, financing of drugs is included in the global budget.

Private for-profit hospitals

The OQN includes a per diem rate covering the consumption of drugs.

3.1.4. Future hospital drugs financing system

The objective is to integrate financing of drugs into the prospective payment per GHS.

3.1.5. Hospital drugs financing system: exceptions

Public and private non-profit hospitals: current system

The financing of drugs is not included in the global budget in two cases:

- expensive and innovative drugs; and
- hospital drugs sold to ambulatory patients.

In the case of innovative drugs, manufacturers enjoy a monopoly position that does not allow hospitals to negotiate good prices. These products under monopoly (such as new antiretroviral drugs and new anti-cancer drugs) represent 80% of hospital drugs expenses. In order to ensure hospital (and therefore patient) access to these expensive and innovative drugs, the Ministry regularly adds funds on top of the global budget[6,7]. These funds can be specific ("Crédits Fléchés" in 2001, 2002 and 2003 for innovative anti-cancer drugs such as Trastuzumab–Herceptin, Rituximab-Mabthera, and Imatinib – Glivec and "Crédit Fléché" for the treatment of the rheumatoid arthritis by Remicade - Infliximab in 2002 and 2003) or not (general fund for innovative drugs in 2002)[8,9]. Several criticisms are made against these "Crédits Fléchés". They are not equally distributed (an important part is attributed to academic hospitals) and it could lead to inequality in patient access to care. They are sometimes used to finance other activities. Last but not least, there is few[c] evaluation of their impact and of their usefulness[10].

In the second case, drugs which can only be sold in hospitals but can be acquired by ambulatory patients in hospital pharmacies, are paid by health insurance funds to hospitals. This process is called "retrocession" and is only applicable to "drugs reserved for hospital use". Until recently there were no criteria or restricted lists for this type of drugs. Some manufacturers asked for this status in order to bypass the price regulation applicable to drugs sold in community pharmacies[10]. This process was also used by some hospitals to transfer the burden of financing drugs to health insurance funds. From 2000 to 2003, expenses of the main insurance health funds for retrocession products doubled[6].

Private for-profit hospital: current system

Blood-derived drugs are not included in the per diem rate and are reimbursed separately on a fee-for-service basis.

Chemotherapy drugs given to hospitalized patients are included in a specific per diem rate. Chemotherapy drugs given to ambulatory patients are reimbursed separately on a fee-for-service basis[11].

Future system[6]

Expensive drugs

In principle, the objective is to integrate financing of drugs into the prospective payment per GHS.

Nevertheless, some expensive innovative drugs will be paid by health insurance funds on top of the new per case payment system.

A first list of these drugs has been elaborated in March 2004 (see appendix I) and will be reviewed regularly by the Ministry of Health, the Ministry of Social Security and the "Agence Technique de l'Information sur l'Hospitalisation" - ATIH. In order to be integrated in this list, a drug has to be expensive and its prescription has to be highly variable into a GHS (and thus induce cost heterogeneity into a GHS).

An agreement between pharmaceutical companies and the Economic Committee of Health Products ("Comité Economique des Produits de Santé" – CEPS) will set up a ceiling price for

[c] In the Region of "Provence-Alpes-Côte d'Azur", attribution of the anti-cancer drugs specific fund to the hospitals is conditionally linked to the compliance with guidelines set up for Trastuzumab – Herceptin, Rituximab – Mabthera, and Imatinib – Glivec[8].

these drugs to be sold to hospitals. This ceiling price will also be the one on which the health insurance reimbursement level is based. It can be decreased if the national target for health expenditure is exceeded. This price regulation is motivated by the sharp increase of expenses which is challenging the access to innovative treatments.

This new system will probably lead manufacturers to adopt new strategies. If a product is included in the list of expensive drugs, its price will be regulated. Otherwise, the drug price will be negotiated directly with the hospital (which is theoretically a less powerful purchaser than the Economic Committee). But the payment for the drug will be included in the per case rate, which means that its utilisation will be compared with alternative treatments.

In order to be fully reimbursed for the cost of these drugs, hospitals will have to agree with the ARH on a "good drug utilization" contract ("contrat de bon usage"). If they don't, they will only be compensated up to 70% of their expenditure. This type of contract is not clearly defined. It can for example include a set up of guidelines, a nominative prescription or a future computerization of drugs delivering[5].

In order to be included in the expensive drugs list, a drug needs to have received a commercial authorization ("Autorisation de Mise sur le Marché" – AMM). If the drug has only a temporary authorization of use ("Autorisation Temporaire d'Utilisation"- ATU)[d], it has to be financed by a specific fund. This fund ("enveloppe de financement des Missions d'Intérêt Général et d'Aide à la Contractualisation" - MIGAC) will be created to finance specific topics such as education, research and innovation missions. It will be managed by the ARH[5].

Retrocession drugs

A ceiling price will be fixed for these drugs by an agreement between pharmaceutical companies and the Economic Committee of Health Products. A limited list of retrocession drugs has been elaborated (see appendix II) and will be reviewed regularly by the Ministry of Health.

[d] Authorization delivered to new drugs that provide for the first time a treatment for serious or rare diseases.

Appendix I: list of expensive and innovative drugs which will be paid by health insurance funds on top of the new per case payment system*.

Dénomination commune internationale **(Common international name)**	Nom commercial de la spécialité **(Commercial name)**
153Sm-Samarium acide	Quadramet
89Sr-Strontium chlorure	Metastron
Agalsidase Beta	Fabrazyme
	Replagal
Aldesleukine	Proleukin
Alemtuzumab	Mabcampath
Amifostine	Ethyol
Amphotericine B	Abelcet
	Ambisome
Antithrombine III	Aclotine
Arsenic trioxyde	Trisenox
Bosentan	Tracleer
Busulfan	Busilvex
Carglutamique acide	Carbaglu
Carmustine	Bicnu
Caspofungin	Cancidas
Cladribine	Leustatine
Complexe prothrombique active	Feiba
Darbepoetine Alfa	Aranesp
Daunorubicine	Daunoxome
Dexrazoxane	Cardioxane
Docetaxel	Taxotere
Doxorubicine	Caelyx
	Myocet
Drotrecogine alfa	Xigris
Epirubicine	Farmorubicine
Epoprostenol	Flolan
Eptacog alfa (active)	Novoseven
Erythropoietine	Eprex
	Neorecormon
Esthers ethyliques d'acides gras iodés	Lipiocis
Ethanercept	Enbrel
Facteur VII de coagulation	Facteur VII LFB

Dénomination commune internationale **(Common international name)**	Nom commercial de la spécialité **(Commercial name)**
Facteur VIII de coagulation	Factane
	Helixate Nexgen
	Hemofil M
	Kogenate Bayer
	Monoclate
	Recombinate
	Refacto
Facteur IX de coagulation	Betafact
	Mononine
Facteur Von Willebrand et Facteur VIII de coagulation en association	Facteur Von Willebrand LFB
	Innobranduo
Facteur XI humain	Hemoleven
Facteurs de coagulation IX, II, VII et X en association	Kaskadil
Fludarabine	Fludara
Fotemustine	Muphoran
Gemcitabine	Gemzar
Idarubicine	Zavedos
Iloprost	Ventavis
Imiglucerase	Cerezyme
Immunoglobuline anti hépatite B	Ivhebex
Immunoglobuline antilymphocite	Lymphoglobuline
Immunoglobuline antithymocyte	Thymoglobuline
Immunoglobulines humaines polyvalentes, pour administration intravasculaire	Endobuline
	Gammagard
	Octagam
	Sandoglobuline
	Tegeline
Infliximab	Remicade
Inhibiteur C1	Esterasine
Irinotecan	Campto
Laronidase	Aldurazyme
Nonacog Alfa	Benefix
Oxaliplatine	Eloxatine
Paclitaxel	Taxol
Pentostatine	Nipent
Phenylbutyrate sodique	Ammonaps
Pirarubicine	Theprubicine
Porfimer sodium	Photofrin
Protéine C	Ceprotin
	Protexel
Raltitrexed	Tomudex

Dénomination commune internationale **(Common international name)**	Nom commercial de la spécialité **(Commercial name)**
Rasburicase	Fasturtec
Rituximab	Mabthera
Thyrotrophine	Thyrogen
Topotecan	Hycamtin
Trastuzumab	Herceptin
Vinorelbine	Navelbine
Voriconazole	Vfend

* From: http://www.sante.gouv.fr/htm/dossiers/budg_etab2004/annexe2.pdf [updated 15/10/2003; accessed 10/10/2004]

Appendix II: List of retrocession drugs. Ministerial Decree of October 27, 2004**

Nom de la spécialité **(Substance name)**	Titulaire de l'autorisation de mise sur le marché **(Owner of the commercial authorization)**
1. Aranesp, Eprex, Néorécormon	
Aranesp (tous les dosages et les présentations)	Amgen
Eprex, solution injectable (tous les dosages et les présentations)	Janssen Cilag
Néorecormon (tous les dosages et les présentations)	Roche
2.Médicaments dérivés du sang et analogues recombinants	
Facteur VIII de coagulation humain	
FACTANE 100 U.I./ml, poudre et solvant pour solution injectable	LFB
HEMOFIL poudre et solvant pour solution injectable	BAXTER
MONOCLATE, poudre et solvant pour solution injectable	Aventis Berhing
Facteur VIII de coagulation recombinant = octocog alfa (DCI)	
ADVATE, poudre et solvant pour solution injectable	Baxter AG
HELIXATE NEXGEN, poudre et solvant pour solution injectable	BAYER AG
KOGENATE BAYER, poudre et solvant pour solution injectable	BAYER AG
RECOMBINATE, poudre et solvant pour solution injectable	BAXTER
REFACTO, poudre et solvant pour solution injectable	Wyeth Europa
Facteur IX de coagulation humain	
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	LFB
MONONINE, poudre et solvant pour solution injectable	Aventis Berhing
NONAFACT 100 UI/ml, poudre et solvant pour solution injectable	Sanquin
OCTAFIX 100 UI/ml, poudre et solvant pour solution injectable	OCTAPHARMA
Facteur IX de coagulation recombinant = nonacog alfa	
BENEFIX, poudre et solvant pour solution injectable	Wyeth Europa
Facteur VII de coagulation humain	
FACTEUR VII LFB 500 UI/20ml, poudre et solvant pour solution injectable	LFB
Facteur VII de coagulation recombinant = eptacog alfa (activé)	
NOVOSEVEN, poudre et solvant pour solution injectable	Novo Nordisk
Facteurs de coagulation ayant une activité court-circuitant l'inhibiteur du facteur VIII	
FEIBA, poudre et solvant pour solution injectable	BAXTER
Facteur XI de coagulation humain	
HEMOLEVEN 1000 U/10 ml, poudre et solvant pour solution injectable	LFB
Facteur Willebrand de coagulation humain	
FACTEUR WILLEBRAND LFB 1000 UI/20ml, poudre et solvant pour solution injectable	LFB
WILFACTIN 100 UI/ml, poudre et solvant pour solution injectable	LFB
Facteur Willebrand de coagulation humain + facteur VIII de coagulation humain	
INNOBRANDUO, poudre et solvant pour solution injectable	LFB
WILSTART, poudres et solvants pour solution injectable	LFB
Facteur X + facteur II + facteur VII + facteur IX de coagulation humain	
KASKADIL, poudre et solvant pour solution injectable	LFB
Immunoglobuline humaine normale	
ENDOBULINE 50 mg/ml, poudre et solvant pour solution injectable	BAXTER
GAMMAGARD 50 mg/ml, poudre et solvant pour solution pour perfusion	BAXTER
OCTAGAM 50 mg/ml, solution pour perfusion	OCTAPHARMA
SANDOGLOBULINE, poudre et solvant pour solution pour perfusion	ZLB
TEGELINE 50 mg/ml, poudre et solvant pour solution pour perfusion	LFB

Nom de la spécialité **(Substance name)**	Titulaire de l'autorisation de mise sur le marché **(Owner of the commercial authorization)**
Antithrombine III humaine	
ACLOTINE 100 UI/ml, poudre et solvant pour solution injectable	LFB
Inhibiteur de la C1 estérase humain	
ESTERASINE 50 U/ml, poudre et solvant pour solution injectable	BAXTER
Protéine C humaine	
CEPROTIN, poudre et solvant pour solution injectable	BAXTER
PROTEXEL 50 UI/ml, poudre et solvant pour solution injectable	LFB

**From : http://www.sante.gouv.fr/htm/dossiers/retrocession/retro42.htm

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3.2. GERMANY

Since January 1, 2004 a mandatory DRG (Diagnosis Related Groups)-based hospital reimbursement system has been introduced in Germany. Under the DRG system the hospital receives a lump-sum compensation per patient based on the diagnosed illness, regardless of the length of hospital stay. Before 2004, German hospitals were financed mainly on a per diem basis.

We first describe the structure of the hospital sector and the hospital financing scheme before 2004. Next, we summarize the main characteristics of the German DRG (G-DRG) system. The reimbursement of hospital drugs in the previous and current system is described in sections 3.2.3 and 3.2.4. The financing of expensive hospital drugs is discussed in section 3.2.5.

3.2.1. Previous hospital financing system (1985-2003)

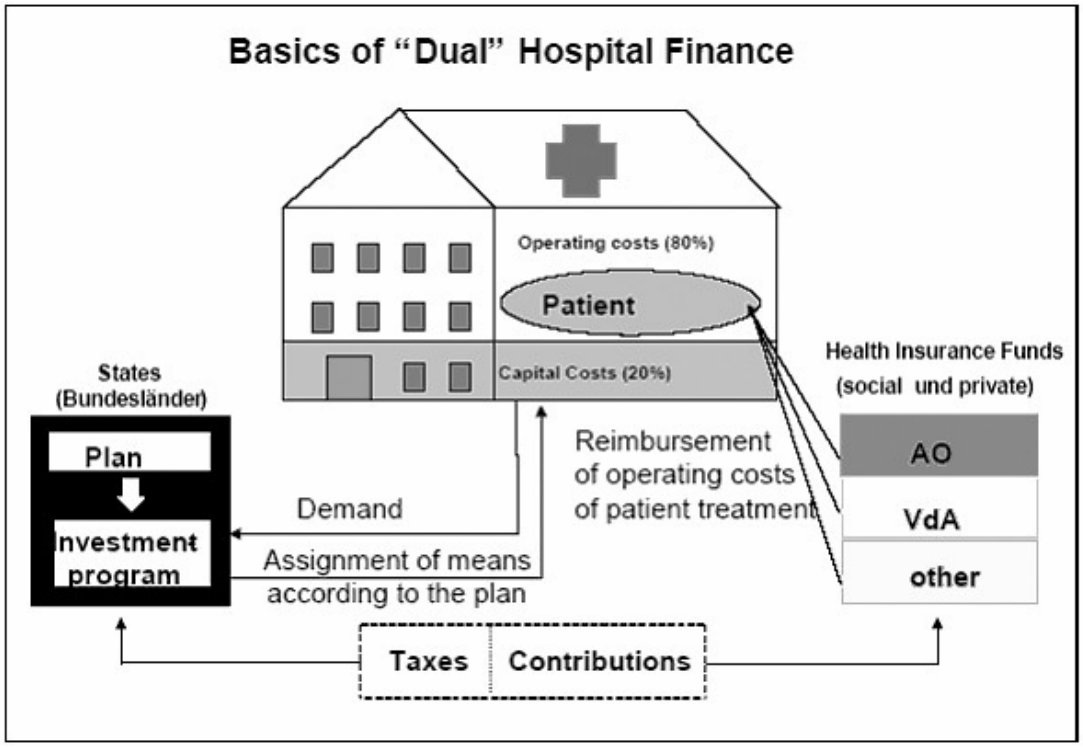
Hospitals

The hospital sector in Germany can be classified according to the type of ownership: public, private non-profit or private for-profit. Public hospitals are owned by public authorities at the federal, state ("Land"), regional or community level. An important category are the university hospitals which are run by states, while public general hospitals are usually owned by a municipality. Private non-profit hospitals are owned by churches, welfare organizations, foundations… Private for-profit hospitals, often owned by doctors, are subject to the same financing and payment rules as the non-for-profit private or public hospitals if they treat statutory health insurance (SHI) members[1,2,3]. In 2001 the general hospital sector consisted of 723 public hospitals, 804 private non-profit hospitals and 468 private for-profit hospitals. There were also 35 university hospitals. Total hospital capacity in the three categories of general hospitals was 516000 beds: 277000 (53,7%) were publicly owned, 198000 (38.4%) were private non-profit and 41000 (7.9%) were for-profit beds.

Hospital care in Germany has been the responsibility of the Länder since 1972. The Hospital Financing Act of 1972 ("Krankenhausfinanzierungsgesetz" - KHG) introduced a dual financing system for hospital capital and operating costs and a full cost cover principle[4,5,6]. Dual financing refers to a system where a distinction is made between the funding of capital costs and the funding of operating costs (see Figure 1, from Neubauer[6] on p14). The financing of capital costs (hospital buildings, beds and medical equipment) is the responsibility of the Länder[a]. To be eligible for capital funding, hospitals have to be listed in the hospital plans set by the Länder. The annual hospital plan of a Land defines each hospital's capacity in the form of specialist departments ("Fachabteilung") and the number of beds per specialty[3,4,6]. Private for-profit hospitals are also entitled to funding if they are incorporated into the hospital plan of their Land. About 80% of all private for-profit hospitals were plan hospitals in 2003. Operating costs on the other hand are covered by sickness funds and private insurance[2,4]. The operating costs include all personnel costs, since hospital specialists are salaried employees of the hospitals [7,b].

[a] Between 1972 and 1985 the responsibility for capital costs was shared by the Bund and the Länder.
[b] In the next sections we limit the description of the German hospital (drugs) financing scheme to the operating costs incurred by sickness fund patients.

Figure 1: Dual hospital financing



The full cost cover principle meant that all operating costs incurred by sickness fund patients were fully reimbursed by the social and private health insurance funds and by patients' co-payments. The actual remuneration was done through per diem charges retrospectively calculated on the basis of total operating costs of the previous year, by the Länder for each hospital.

Although a series of cost-containment laws were adopted in the mid-eighties, in practice the full cost cover principle of operating costs dominated the financing of German hospitals until 1995. The first cost-containment law, the 1985 Hospital Restructuring Act ("Krankenhausneuordnungsgesetz" - KHNG), introduced prospectively negotiated per diem charges. Starting in 1985, the "flexible" prospective budgeting[c] system meant that only the costs of "economically operating and efficient[d]" hospitals were fully reimbursed. The flexible hospital budget was the result of negotiations between local sickness funds and the hospital and was calculated on the basis of anticipated occupancy rates in the next year and of the costs per day[2,8]. This means that the actual remuneration was done through prospectively negotiated per diem charges based on expected costs. When the actual number of inpatient days delivered (ex post) exceeded the planned (ex-ante) number, hospitals received only 25% of the per diem rate on the excess number. When the actual number fell short of the expected inpatient days, the hospital received 75% of the per diem for the missing days in the next round of the budget negotiations. So hospitals were no longer reimbursed for all their operating costs.

The Health Care Structure Act ("Gesundheitsstrukturgesetz" - GSG), which became effective on January 1, 1993, made an end to the flexible budgeting system and required from the year 1993 on a "fixed" or "capped" prospective hospital budget. The fixed budgets could no longer be adjusted to compensate (partially) for the difference between actual and negotiated bed days. The 1992 budget of each hospital was used as the base, with the average income growth of the SHI members as the only allowed adjustment. Yet, during this transitional budgeting phase until 1995 there were many exceptions to the rigid budget cap, especially concerning the cost of personnel. Over the medium term, the GSG replaced the full cost coverage by a system based on

[c] The specialists' earnings for treating private patients in hospitals and the hospital revenues from elective services for which patients are charged directly are not included in the budget.
[d] Efficiency was measured by comparing the costs and activity data of similar groups of hospitals with respect to types and intensity of care.

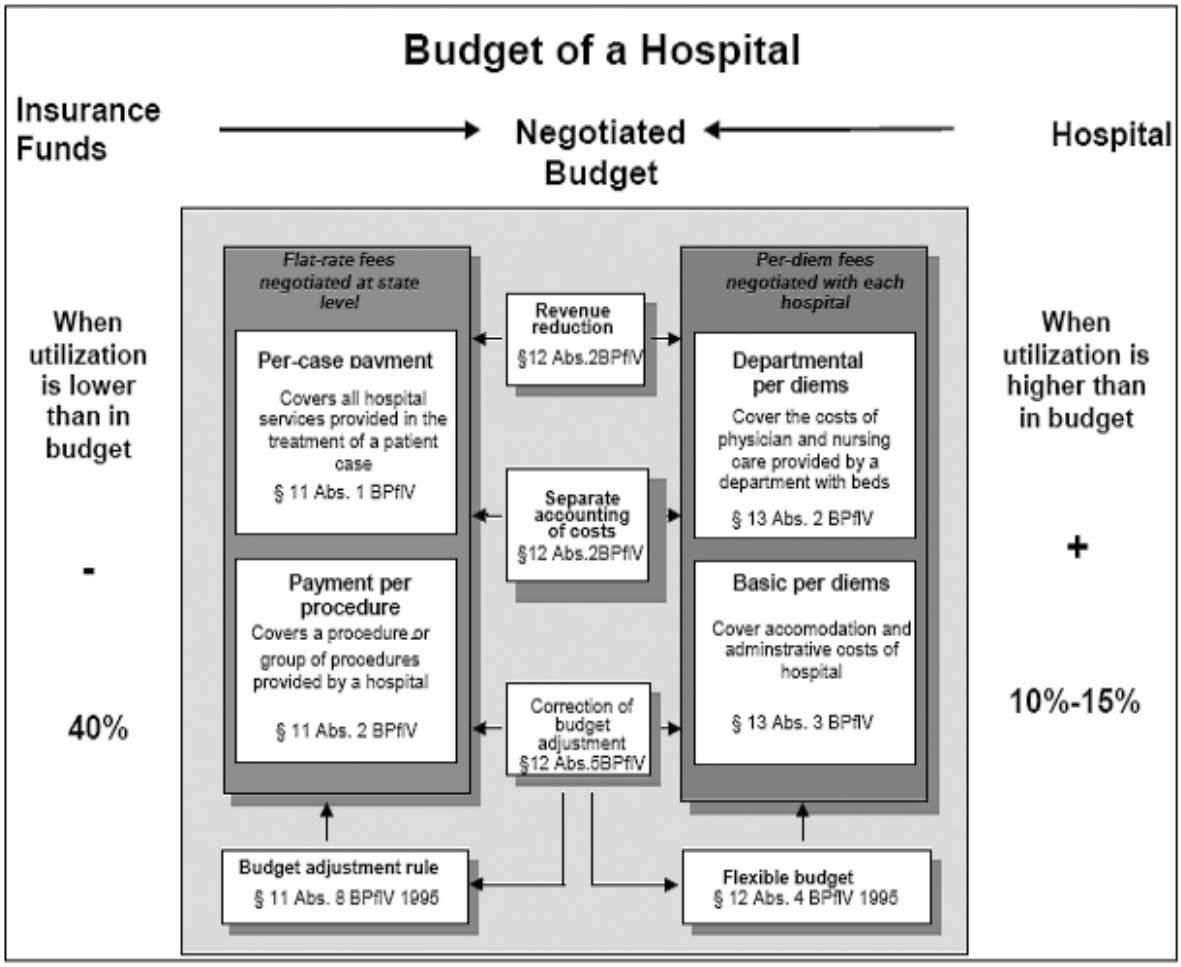
prospective and service-oriented fees[4,6,7]. The Hospital Rate Ordinance of 1995 ("Bundespflegesatzverordnung" – BPflV 1995) worked out the details of the GSG and established the rules for the hospital financing reforms[e] (in force since January 1, 1996[f]).

Figure 2 (Neubauer[6] on p18) illustrates the different components of a hospital's annual budget as defined in the BPflV of 1995. The level of a hospital's budget and the scheduling of the different payment components were subject to negotiations between the (local) health insurance funds and the hospital[g]. From 1996 prospective lump-sum payments per case ("Fallpauschalen") and procedure fees ("Sonderentgelte") were introduced for a limited list of inpatient treatments[5]. The values of the procedural and case-based fees were determined at the national level and were based on an empirical analysis of the average costs in a sample of hospitals. The total amount paid for procedures and services covered by both fees was negotiated yearly at state level so that the payment for a certain treatment was the same for all hospitals in the same state[6]. The case-based lump-sum payments were supposed to cover the total cost -medical and non-medical- of inpatient care for a particular hospital admission. Only a maximum length of stay was covered in a case fee. If the actual length of stay exceeded this maximum, the case was considered as an outlier and the extra days were reimbursed on the basis of per diem rates. The procedure fees had to cover the costs of specific procedures, including the costs of implants, transplants, laboratory and surgical services used during a procedure. The proportion of cases reimbursed through prospective case fees was less than 25 percent. However, there were wide variations both between hospitals and between specialties. The number of different case fees and procedure fees as well as the volume provided was negotiated between the health insurers and the hospital.

All other cases were reimbursed by a two-tier system of per diem charges: a flat hospital-wide rate ("Basispflegesatz") covering non-medical costs and department specific charges ("Abteilungspflegesatz") covering medical costs. The department specific per diem was paid for each inpatient day in the respective department. Hence the total budget of each hospital consisted of case fees, procedure fees and per diem charges. The budget was however not an amount of money for a hospital independent of actual activity. Instead, the budget was the result of negotiations between the health insurers and the hospital and was the target for the next year. The basis per diem for non-medical services was negotiated separately. The base line for the negotiations was the hospital's budget from the previous year. Actual activity could diverge from the target activity. If actual activity was higher, then the hospital had to pay back a certain part of the received reimbursement. The percentage to be reimbursed varied between the different payment methods: 75 percent of case and procedure fees[h] and 85-90 percent of per diems. If actual activity resulted in a lower budget than the target budget, it received 40 percent of the difference. This means that the "fixed" hospital budget was only fixed if the hospital actually provided the type and volume of services agreed upon in the budget negotiations[5,6].

[e] The reforms relate only to the operating costs of acute care hospitals[3]. Since then there have been several reforms and adjustments to the GSG.
[f] Individual hospitals were allowed to implement the new financing system on January 1, 1995[2].
[g] We limit the overview to the budget and reimbursement mechanism for full inpatient stays and neglect special arrangements for e.g. short-term stays, ambulatory care before and after an inpatient treatment.
[h] For transplantations only 50 percent of the case fees had to be paid back.

Figure 2: The different components of a hospital budget



Specialists

In general, hospital specialists are paid a salary by the hospital. Private patients can be charged for hospital services according to a federal fee schedule. The head physician of a unit collects all revenues from private patients and, depending on the specific hospital law, distributes part of it to a pool on a voluntary or mandatory basis. Hospital specialists also have to give up part of their revenues to compensate the hospital for the use of hospital facilities. Before the GSG 1993 reimbursement rules were part of the contract between the head physician and the hospital management. The GSG 1993 mandated that in general 40% of private fees had to be included in the hospital's budget as costs already reimbursed.

Problems with the current system

The main problems with the dual financing system that led to the introduction of major reforms, were the following[6]. Firstly, the mixture of per case payment and per diem rates for the reimbursement of hospital services reduced the incentives to shorten the length of stay. Secondly, hospitals had few incentives to increase efficiency since there was no clear connection between the provision of services and reimbursement. Although officially abandoned in 1985 with the introduction of a prospective budgeting system, hospital financing remained largely based on the principle of cost reimbursement. And thirdly, the dual financing system split the responsibility between the Länder (who determine the capacities of the hospital sector) and sickness funds (who are responsible for the operation and financing of the hospital sector).

3.2.2. New hospital financing system: DRG reimbursement system (2004)

The SHI Reform Act ("Gesundheitsreformgesetz" - GKV 2000) introduced a complete new system for the reimbursement of the operating costs of hospitals. The new payment system is based on case fees -for inpatient cases- which are uniform for all hospitals[5]. Psychiatric hospitals or wards are excluded. The main objectives of the reform were the improvement of transparency and quality, a decrease in the length of stay and an elimination of unused capacities. Other reform measures for the hospital sector were the introduction of a technology assessment committee to evaluate the cost and efficiency of medical technology and the strengthening of the role of clinical guidelines[i,6]. Although the Reform Act did not prescribe a specific reimbursement system per se, the lawmakers obviously referred to a DRG-type system. The actual decision was left to negotiations between the federal hospital organisation ("Deutsche Krankenhausgesellschaft" - DKG) and the association of sickness funds and private insurers. They opted for the Australian Refined DRG-system (version 4.1) adapted to German cost data. The AR-DRG system is a refined DRG system which heavily relies on weighting complexities and co-morbidities and takes into account procedures (and thus treatment decisions). The new reimbursement system will be introduced in phases[3]. After a budget neutral [j] optional introduction for all interested hospitals in 2003, a mandatory implementation – also budget neutral - for all hospitals came into effect on January 1, 2004. While the Australian system uses 661 DRGS, the actual number of G-DRGs used is 824 in 2004 and 878 in 2005. The Australian cost weights were adapted and changed rather immediately by the G-DRG institute, the InEK ("Institut für das Entgeltsystem im Krankenhaus")[k]. The G-DRGs and cost weights are to be adapted on a yearly basis.

After the hospital budget neutral years in 2003 and 2004, a period of convergence between the old and the new DRG-based budget follows over the five years[l] in which the individual hospital base rate has to adjust to the federal state base rates. Hospital specific base rates are calculated as the (1992) budget for all services which now fall under DRGs (of a hospital) divided by (the CMI * number of patients). The CMI (case-mix index) is calculated as the sum of the relative weights of all DRGs of a hospital divided by the number of patients. From 2009 onwards the base rates will be negotiated ex-ante at the level of the Länder between the health insurance fund associations and the hospital management. Land-specific base rates must be based on the average reimbursement amount of all DRGs in a Land.

The structure of the German DRG-system is identical in all states. The relative weights of the G-DRGs are calculated nationwide as the average of the costs per case of a sample of hospitals (with supplying cost centre accounts). Hospitals with individual base rates above the average will be forced to cut their costs, while hospitals with lower than average base rates will build surpluses.

Supplementary payments are possible for e.g. the costs of nurses' education. Hospitals also receive grants for a list of specific procedures and a per diem for outlier cases. The only relevant variable for the reimbursement of low and high outliers is the length of stay. For hospital stays falling outside the low and high boundary points, the amount that is reimbursed per day is lower than the normal DRG payment.

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[i] Health Technology Assessment committee of the DIMDI (German Institute of Medical Documentation and Information – Deutsches Institut für Medizinische Dokumentation und Information).

[j] Budget neutral means that total expenditure on hospitals may not be larger or smaller than in the current system. The existing hospital budget applies, although it is allocated according to cases instead of days.

[k] The G-DRG institute has been implemented by the federal associations of the sickness funds, the DKG (the main body representing the hospitals) and the federal association of private health insurers to support them in their duty (stipulated by law) to implement and develop the G-DRG based reimbursement system. The institute is financed by an overhead on the DRGs.

[l] The 2. Fallpauschalenänderungsgesetz (2.FPÄndG) has been adopted by Parliament on November 25/26, 2004. This law prolonged the period of convergence, which was originally planned to last three years, to five years (until 2009).

3.2.3. Previous hospital drugs financing system

As mentioned in section 3.2.1 a mixed reimbursement system was introduced in 1996, with prospective case-based reimbursement by fixed prices for certain clearly defined surgical operations and per idem charges for all other services coexisting. The per diem charges consisted of a flat-rate per hospital ("Basispflegesatz") for non-medical costs and a department-specific additional rate ("Abteilungspflegesatz") covering medical costs including nursing, procedures and drugs. There was no extra payment for expensive drugs.

The prices of hospital drugs are freely negotiable by each hospital with the pharmaceutical industries[9].

In general hospitals negotiate directly with the industries. In some case hospitals merge into purchasing groups so that they are in a better position to enforce larger discounts.

3.2.4. Hospital drugs financing in the new G-DRG system

In general the cost of hospital drugs is included in the calculation of the relative weight of each DRG.

The reimbursement of new drugs (and other new technologies) is regulated by law ("Krankenhausentgeltgesetz", 2002, p1426). A special reimbursement for new treatments/drugs will be made for the first time in 2005. Hospitals have to make a request at the InEK for the extra amount before September 30, 2004 (and before September 30 of every year in the future). The special reimbursement for these new drugs or treatments, if accepted by the InEK, is valid only for one year. The rule for acceptance is that the costs of the new drug must be so expensive that the DRG reimbursement is not adequate to compensate for the cost of the treatment including the new drug. For new drugs not applied for before September 30, 2004, the hospital can ask the local sickness fund if it wants to reimburse the new drug (but more likely the drug will be included in the supplementary insurance).

3.2.5. Exceptions for expensive drugs

Although most hospital services are financed through DRGs, for some inpatient services hospitals receive an add-on ("Zusatzentgelte"). The additional reimbursement can be the same for all hospitals or it may be a hospital-specific amount. The Statutes for a flat-rate per case system in hospitals ("Verordnung zum Fallpauschalengesetz für Krankenhäuser" - KFPV 2004) name the inpatient services for which hospitals receive a nationwide or a hospital-specific add-on. In 2004 the only add-on for inpatient drugs was a hospital-specific payment for coagulation factors for haemophiliacs.

In September 2004 the Fallpauschalen-Katalog for 2005 was adopted. There are a few more drugs which are financed separately from the DRG reimbursement. The following drugs are eligible for being additionally reimbursed by an amount which is the same for all German hospitals:

- Alemtuzumab (parenteral administration (pa))
- Caspofungin (pa)
- Docetaxel (pa)
- Filgrastim (pa)
- Gemcitabin (pa)
- Human-Immunoglobulin (pa, polyvalent)
- Irinotecan (pa)
- Lenograstim (pa)
- Liposomal Amphotericin B (pa)
- Methotrexate (pa)

- Oxaliplatin (pa)
- Paclitaxel (pa)
- Rituximab (pa)
- Topotecan (pa)
- Trastuzumab (pa)
- Voriconazole (oral)
- Voriconazole(pa)
- Prothrombine complex (pa)
- Antithrombin III (pa)
- Erythrocytes concentrates
- Thrombocyte concentrates
- Thrombocyte Apheresis concentrates
- Patient-specific Thrombocyte concentrates

Drugs which will be additionally reimbursed by a hospital-specific amount in 2005 are:

- Coagulation factors for haemophiliacs
- Adalimumab (pa)
- Gemtuzumab Ozogamicin (pa)
- Human-Immunoglobulin (Zytomeglie-Virus) (pa)
- Human-Immunoglobulin (Varicella-Zoster-Virus) (pa)
- Infliximab (pa)
- Sargramostim (pa)
- Granulocyte concentrates

To be eligible for expensive drug reimbursement, the expensive drug should be present in more than one DRG. If on the other hand an expensive drug is only relevant for one DRG, the cost weight of that specific DRG should be adapted. The decision on the qualification for supplementary reimbursement is taken by the G-DRG institute (InEK) on the basis of an evaluation of the costs. The selection of hospitals that qualify for the hospital-specific amount is also done by the G-DRG institute. While the amount of the nation-wide additional reimbursement is determined by the InEK, the amount of the hospital specific add-on is the result of negotiations between the hospital and the regional sickness funds.

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3.3. SWITZERLAND

The financing scheme of Swiss hospitals is highly variable according to their status and to the canton where they are located. The federal government is planning a reform to implement a general prospective payment system based mainly on case-mix.

The first section explains the various existing financing systems. The second section describes the reforms planned. Next we explain the way hospital drugs are financed in the current hospital financing scheme and the reforms envisaged. We conclude with the description of the specific Swiss treatment of expensive drugs.

3.3.1. Current hospital financing system

The Swiss health system has a strong federalist character and consequently no uniform structure. Instead, the whole health care sector comprises 26 slightly different systems, corresponding to the number of cantons and half-cantons. As a rule, the federal government enacts framework laws, while responsibility for regulations and implementation is transferred to the cantons and local authorities.

In the area of health insurance, the federal government has legislative and supervisory powers. Since 1996, all Swiss residents are required to purchase basic insurance cover.

Swiss residents can also purchase voluntary complementary insurance to obtain more comfortable accommodation in hospital or to choose freely their physician in case of a hospital stay.

Swiss hospitals can be public, private but publicly subsidized or private and non-subsidized. Public hospitals may be operated by the canton in which they are located, municipalities, or independent foundations[1,2].

Hospitals are financed differently according to their status and according to the type of room (private, semi-private or shared room).

Hospital financing system according to their status and type of room or type of hospitalization[a]

	Public or publicly subsidized hospitals	Private hospital
Shared room ("division commune")	- Maximum 50% of operating costs are financed by compulsory insurance funds (actually they finance from 43% to 47% of operating costs). Payment system: lump sums - The rest of operating cost is financed by cantons. Payment system: lump sums or global budget or financing of hospital's deficit. - Construction, investment, research and training costs are subsidized by cantons.	Operating and investment costs are financed by private insurers. Payment system of operating costs: lump sums (according to contract, regularly two times the lump sums paid by compulsory insurance funds for the shared rooms ("division commune") of public or publicly subsidized hospitals).
Private or semi-private room	- Compulsory insurance funds finance maximum 50% of operating cost related to the shared rooms ("division commune") of hospitals (costs specifically related to the private status of the room are covered by private insurers). Payment system: lump sums - The rest of operating cost related to the shared rooms ("division commune") is financed by cantons. Payment system: lump sum or global budget or financing of hospital's deficit.	- Compulsory insurance funds finance some of the operating costs Payment system: lump sums - The rest of operating costs and the investment costs are financed by private insurers. Payment system of operating costs: usually fee-for-service, sometimes lump sums.

[a] Based on information provided by the Swiss Conference of the Cantonal Ministers of Public Health, Bern.

	- Additional operating cost, related to the private status of the room, are financed by private insurers or by the patient. Payment system: usually fee-for-service, sometimes lump sums.	
Short in-patient stay (less than one night) and outpatient care	Financed by compulsory insurance funds, and not subsidized by the cantons. Payment system: fee-for-service (TARMED schedule)[b]	Financed by private insurers, and not subsidized by the cantons. Payment system: fee-for-service (TARMED schedule)

The type of lump sum paid by compulsory insurance funds in order to finance operating costs varies amongst cantons and hospitals. Indeed, rates are prospectively negotiated on a canton-wide level between health insurance fund associations and organizations of service providers (such as hospital associations), but hospitals often negotiate individually their contracts. The agreements that result from the negotiations vary considerably.

For example in 2004, for public and publicly subsidized hospitals, the type of lump sum paid was[3]:

- a daily lump sum in hospitals from 9 cantons;
- a lump sum per case (defined by department – "abteilung" - or by patient path) in hospitals from 4 cantons;
- a lump sum per case (defined by department) + a daily lump sum in hospitals from 11 cantons;
- a lump sum per patient path (a case-mix system different of the AP-DRG[c] system); and
- a lump sum per AP-DRG in hospitals from 3 cantons.

Lump sums per case are defined by department such as surgery, internal medicine, orthopaedics, paediatrics, and obstetrics. The classification of departments may vary amongst hospitals.

From 2005 to 2006, the introduction of a lump sum per AP-DRG is planned in public hospitals from 11 cantons. Therefore, in 2006 the AP-DRG case-mix system will be in use in 14 cantons.

Costs covered by lump sums in public and publicly subsidized hospital's shared rooms ("division commune") are medical fees, drugs, accommodation costs in a shared room and nursing costs. The same types of costs are covered by lump sums in private hospital's shared rooms, but lumps sum are higher or even doubled according to the contracts negotiated between private insurers and hospitals.

The range of costs covered by lump sums in hospital's private or semi-private rooms varies also amongst cantons and amongst hospitals. Some medical fees, drugs, intensive care, implants, expensive procedures like transplantation and heart surgery are not always included in the lump sums and can be billed separately[3].

Problems with the current system

The Swiss system is highly complex. The financing system of hospitals, the type of payment to hospitals and, in case of a flat-rate payment system, the costs covered by flat-rates vary amongst cantons at a national level, amongst hospitals at a cantonal level and amongst types of room at the hospital's level. It is difficult to compare hospital costs and therefore their efficiencies.

Moreover, private and public hospitals have different reimbursement systems. This difference in financing could generate inequalities in incomes and in care supply.

[b] TARMED is a new national schedule implemented in January 2004. This schedule is applied to each medical ambulatory service provided in a private office or in a hospital. Point values are determined on a national scale for 4600 medical services. The price attached to the point value is then negotiated at a cantonal level. Hospitalizations of less than one night are considered as "semi-ambulatory services", and the TARMED schedule is therefore applied.

[c] All Patient Diagnosis Related Group.

Cantons do not provide subsidies for outpatient and short stay inpatient care (less than one night). In contrast, inpatient hospital care (of one or more than one night) receives public subsidies.

This results in a system that does not always provide incentives for the most appropriate health care and the most economically efficient organisation. There could be an incentive for health insurance funds to favour inpatient treatment since some of the cost is born by the state[1].

3.3.2. Future hospital payment system

The Swiss Federal Parliament is discussing a reform according to which compulsory insurance companies and cantons would each finance half of operating and investment costs of hospitals. Capital costs would thus have to be covered by the per diem or, preferably, by a payment per case. A reason for the reform is the difference between the reimbursement system of public and publicly subsidized hospitals on one side and private hospitals on the other side, especially for private or semi-private rooms. This discrimination affects competition between hospitals. Moreover, the distinction in the financing system between operating costs and investments costs was not justified because they are highly correlated (and the difference between them is not always clear, in case of leasing for example)[4,5].

The Federal Parliament also asked the federal government within three years to propose a new hospital financing system with a single payer.

Payments per patient-day (i.e. per diem), still used to pay a lot of hospitals, reduce the incentives to shorten the length of stay, and thus provide little incentives for efficiency. The federal government has proposed a revision of the federal law of health insurance which would set up a prospective payment system, based mainly on case-mix. This revision would thus promote and standardize the "payment per case" system, such as diagnosis-related group, which is already used in several cantons. Contractual partners (i.e. providers and insurance companies) will be free to decide which rate to apply for each case. But rates will have to be based on identical structures throughout Switzerland, in order to enable national comparisons[5]. The conditions of implementation of this reform are partially filled up because each hospital is required to establish a discharge summary for every hospitalized patient. This summary includes administrative data (age, sex, date and method of admission and discharge, etc.) as well as the diagnostic codes and surgery codes attributed according to the information recorded in the patient's files. Furthermore, hospitals must record their costs statistics since 2003[6].

A national project named SwissDRG has been launched in May 2004[6]. The objective of the project is to build up a nation-wide hospital payment system based on AP-DRG. The model should be introduced by 2008.

3.3.3. Current hospital drugs financing system

The Federal Office for Public Health ("Office Fédéral de la Santé Publique" – OFSP) draws up a positive list of drugs ("Liste des Specialités"-LS) which can be reimbursed by compulsory health insurance, except for a 10% co-payment. Maximum prices are set for these products. To be on this list, a drug has to be effective, appropriate and cost-effective.

The cost of drugs not on this list is not publicly regulated and must be met by the patient or, if applicable, by supplementary insurance[7].

Payment of hospital drugs in the "specialities list" (and therefore reimbursed by compulsory health insurance) is usually included in the lump sums paid for hospital's common division (shared rooms). Nevertheless, the article 49 al. 2 of the Health Insurance Law ("Loi fédérale sur l'assurance-maladie"- LAMal) specifies that the contractual partners can agree to exclude special diagnostic or technical procedures from the lump sums. This article has been interpreted in some cases (as in the Basel-Stadt canton) to exclude expensive drugs from the lump sum[3].

In the case of private or semi-private rooms, hospital drugs are usually billed separately.

3.3.4. Future hospital drugs financing system

In the future hospital payment system, financing of hospital drugs will in principle be included in the per case rate.

3.3.5. Hospital drugs financing system: exceptions

A specific sub-section of the SwissDRG project is dedicated to the financing of expensive hospital drugs. One of the objectives of this study in preparation is to determine if expensive drugs are concentrated in some AP-DRG or are disseminated amongst many AP-DRG. The results will be used in order to determine whether expensive drugs should be billed separately or if some AP-DRG should be modified according to their treatment cost[6]. At this time of writing the specific methodology to determine these exceptions has not yet been decided upon.

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3.4. THE NETHERLANDS

During the last two decades, the financing scheme of the Dutch hospitals and medical specialists has changed several times. The most fundamental change, however, will be on January 1, 2005 with the introduction of Diagnosis and Treatment Combinations ("Diagnose Behandeling Combinaties" - DBCs). To understand the reasons for changing the financing system for Dutch hospitals, we first give a brief overview of the characteristics and most important changes since the beginning of the eighties of the Dutch hospital sector. In the next paragraphs we describe the way hospital drugs are financed in the current hospital financing scheme and the plans for financing hospital drugs in the DBC system. We conclude with the specific treatment of expensive drugs.

3.4.1. Current hospital financing system (1983-2004)

Hospitals

Acute hospital care in the Netherlands is provided by general, academic and specialist (or categorical) hospitals. About 90% of all hospitals are private, non-profit voluntary institutions. The remaining part is publicly owned, including the 8 university hospitals. For-profit hospitals are still prohibited by law.

During the last two decades, Dutch hospitals have been subject to frequently changing government regulations on reimbursement[1,2]. To keep costs under control, the Dutch government introduced a major reform in the method of financing hospitals in 1983. A global hospital budgeting scheme[a] replaced the retrospective output-based financing system which did not control the volume of hospital services, since hospitals were automatically reimbursed for every medical service. Both physicians and management had an interest in maintaining long hospital stays. Moreover, budget deficits could be solved by temporary surcharges on the per diem rates. The global budgeting system put an end to this open ended funding scheme. Each hospital received annually a prospectively determined budget to cover most of its expenses[b] as negotiated with representatives of private insurers and sickness funds. The main purpose of the new financing system was to increase cost containment incentives and to induce hospitals to provide services more efficiently. Another objective was to increase the decision-making autonomy of the hospital managers by relaxing government regulation. The global budgeting system is a closed-end budgeting system since the budget is set in advance, with the hospital management and specialists deciding on the allocation of the resources within the hospital. In 1983 and 1984 the initial budget level for individual hospitals was fixed and based on their level of (variable) costs in 1982, with only an adjustment for general inflation and wage increases. Although this historical budgeting had certainly some advantages – a rapid adoption of the new system and relatively small shifts in funding among hospitals- , an important drawback was the possible danger of penalizing the more efficient hospitals and rewarding hospitals with high levels of expenditure. In 1985 part of the budget was made variable to take the cost structure of hospitals into account[3]. This system, called the Bredero system, was introduced only for the nursing, administration and housekeeping budgets (30% of the hospital budget).

To address the weaknesses of historical budgeting, a Functional Budgeting (FB) system for general and categorical hospitals was introduced in 1988. The primary goal of introducing functional budgeting was to provide equal budgets to hospitals performing the same functions. The functional budgeting system is based on a normative allocation model and consists of three components: availability, capacity and production relating to fixed, semi-fixed and variable costs. The FB budget together with the location related budget for infrastructure costs make up the acceptable costs of the hospital. The availability component in the FB system is based on the number of potential patients depending on a specific hospital (the size of the polyclinical and clinical catchment area) and relates to the fixed costs of the hospital. The capacity component refers to the semi-fixed costs. These costs are made for nursing (the hotel function), depending on the number of recognised beds, and for the number and category of specialists serving in the policlinic. The production component is established in performance agreements between hospitals and insurers and relates to the projected volume of services to be provided to the

[a] Only for operating expenses; large capital expenses were not included in the budget.
[b] Fees paid to medical specialists were not included in the fixed hospital budget. Also interest and depreciation costs remained fully reimbursed.

insurer's members[c]. These variable costs of the hospital concern the number of hospital admissions, inpatient days, outpatient visits and day-care visits. This enables insurers to exert some influence on the level of the budget and on the care to be delivered. Hospitals and insurers only negotiate on volumes, prices are set by the Central Agency for Health Care Tariffs ("Centraal Orgaan Tarieven Gezondheidszorg" - COTG[d]). Since 1988 the importance of the production component has increased while the share of the availability component decreased. So although there is a budget for the hospital, the evolution of the production over time plays an important role. This evolution made the budgeting scheme again more open-ended since, contrary to the historical budgeting system, the government cannot control the contracted volume of production. At the end of the year the allocated budget and the charges to the insurers are balanced. If total expenditures exceed the prospective budget in a given year, expenditure cuts in subsequent years are needed. The functional budgeting has been revised several times since its introduction in 1988. The most important was a restructuring of the model in order to match the funding and costs per specialism better than before[e]. However, in the FB system, relying on supply regulation and external budgeting, there is no direct relationship between financing and actual costs. Other drawbacks are related to the fact that the costs and the budget are not transparent and that the infrastructure costs are financed separately.

Although the determination of the hospital's budget changed frequently during the last two decades, per diem charges remained the main unit of payment for sickness funds and private health insurers. For inpatient services each hospital developed its own policy in charging the insurers. Some hospitals charged insurers an all-inclusive per diem rate, while others charged insurers separately for different inpatient services.

Over the years, the COTG developed uniform, nation-wide rates for a long list of inpatient clinical services for which hospitals must charge the insurers separately[1]. These ancillary tariffs covered about 1600 treatments or diagnostic activities in the hospital and were close to real average costs. The per diem nursing rate was derived directly from the individual hospital's budget[4].

Medical specialists

Almost all medical specialists in the Netherlands are hospital based. Only a small group of specialists (such as psychiatrists and dermatologists) are allowed to practice also outside the hospital. Hospital specialists deliver inpatient and ambulatory care and day-care in hospitals. Most specialists are independent professionals, only a small percentage is salary based[1,f]. The incomes of the salaried specialists are included in the hospital's budget. Until 2000 the independent medical specialists were paid on a fee-for-service basis and their earnings were not included in the hospital budget. The fees were negotiated between national associations of sickness funds and private insurers and the associations of medical specialists. Although the system was frequently adjusted, it remained fee for service since the income of the medical specialists was linked to the volume of their output[5].

In an attempt to control the expenditure on medical specialist care, from 1995 onwards the financing scheme for specialist care moved from a fee-for-service scheme to a lump-sum budget scheme. In 1995 the Dutch government allowed the medical specialists to participate in local initiatives to negotiate a service volume. The aim of the negotiations between the health insurers, the hospital management and the medical specialists was to fix a budget independent of the volume of services provided but in terms of the number of first polyclinic visits, hospital admissions and day care surgery. The large majority of medical specialists chose to participate in these local initiatives. The lump sum per specialty paid to the hospital was based on the volume of services of previous years (1992, 1993 or 1994). Since 2002, due to a change in the law, the negotiations take place between the hospital management and the health insurers, but in the presence of a representative of the medical specialists.

[c] Since 1992 sickness funds operate nationwide because the regional boundaries of the sickness funds were abolished.
[d] This organisation is now called the CTG-ZAio (College Tarieven Gezondheidszorg/Zorgauthoriteit in oprichting).
[e] Financing of academic hospitals is slightly different from the financing scheme of general hospitals. On top of the Functional Budget, academic hospitals receive a lump-sum for the extra costs of top referential patients and a budget from the Ministry of Education for teaching and research activities.
[f] Medical specialists working in university hospitals are salaried employees.

In 2001 a new arrangement was introduced to reduce waiting lists. The lump sum was linked to the volume provided. If the service volume was lower than negotiated, the medical specialists received less money. If on the other hand the volume was higher than agreed with the health insurers, the hospital could negotiate an extra production volume.

3.4.2. Future hospital financing system (2005-…)

On January 1, 2005 the current system of Functional Budgeting of hospitals and lump sum financing of medical specialists will be replaced by the Diagnosis and Treatment Combination system ("Diagnose Behandeling Combinaties" - DCB)[g]. This new instrument for hospital financing, based on case-mix, illustrates the need to introduce more transparently defined hospital products covered by prices reflecting costs. This accompanied the explicit choice made by the government to change the Dutch hospital funding system from supply-driven to consumer-oriented, based on patient need. In the DBC system health insurers and hospitals will be the main players instead of the government. From 1 January 2005 on health insurers, medical specialists and hospital managers are going to negotiate on the volume, price and quality of care for a selected number of DBCs which account for about 10% of the hospital production.

Coverage of the DBC system

The DBC defines "the whole of the hospital and medical specialist activities and services arising from the demand for care by a patient consulting a specialist in a hospital"[6]. A DBC registers the entire patient process from the initial consultation or examination through the final check-up within a medical specialty. In the "care episode" for a health problem of a patient, both inpatient and outpatient activities are included. Hence, the DBC concept is independent of the setting of the care delivery. In the definition of a DBC, 'activities' means medical and medical support services, including outpatient visits, days of treatment and day-care. This broad definition makes it possible to take into account the fact that some inpatient hospital services are increasingly delivered on an outpatient basis. In other words, the DBC is the product delivered to a patient within a medical specialty, and the price of a DBC includes the costs of the hospital for the use of its resources and the remuneration of the medical specialist(s) for the workload.

Methodology, registration and cost calculation

In the DBC system each product or DBC corresponds to a specific problem in a specific medical discipline[7]. A DBC is a label given by the medical specialist to characterize an individual episode of care and contains information on the type of care, diagnoses and treatments, which makes the number of possible DBC codes enormous. The Dutch medical specialists developed their own coding lists[h] instead of using standard international classifications (because many activities could not be identified, a limited degree of detailing, to anticipate new developments quickly …). To make the negotiations with the insurers easier, DBCs which are similar in care profile, workload and price are clustered into a smaller number of product groups. So DBC product groups should be homogeneous in terms of costs and care profile[i].

The hospital information systems needed to be adapted to register the whole care process from the initial contact with the physician to the discharge of the patient. A DBC registration is a registration of hospital products done by the medical specialists themselves using electronic patient filing systems[8]. While the production component of the FB system identifies only four indicators for performance agreements (admission, day-care, initial outpatient visit and days of treatment), the DBC system divides the provision of care into hundreds of healthcare products. For each health issue of a patient within a specialty the DBC record has a starting date, a diagnosis and therapy recorded by the medical specialist. At the final date of the episode of care the DBC is closed and classified into one DBC product group. This recording resulted in each DBC having a price per hospital - there is no uniform national price per DBC - based on the care profile and the cost structure of the hospital[j]. The cost of each DBC consists of a hospital

[g] This paragraph is a summary based on documents on the DBC website (www.dbczorg.nl).
[h] With each of the medical specialties designing their own coding lists.
[i] In reality it seems rather difficult to reconcile homogeneity of costs and of care profile.
[j] To define the product structure, in 2001 some 40 pilot hospitals started calculating their costs for every activity they performed, including both direct costs (staff, equipment) and indirect costs (overheads). They gathered data on outpatient consultations, nursing days, operations, diagnostic procedures and laboratory investigations[8].

and a specialty component. The hospital component comprises the costs of all hospital activities incurred by the DBC[k], the specialty component is the fee for the medical specialist based on the workload.

Financing of DBCs

Hospitals

In January 2003 hospitals, insurers and medical specialist were offered the opportunity to start negotiations on 17 DBCs (with a very long waiting list) defined by the government. The purpose behind the experiment was to offer them the opportunity to learn how to negotiate on price, quality and volume of the DBCs. On January 1, 2005 10% of the total hospital budget will be subject to market forces (segment B). For the other 90% -segment A- the current FB system will still apply. In segment B DBC prices are the result of negotiations between insurers and the hospital. Hence, the negotiated prices determine the budget in this segment. In segment A however, DBC prices are fixed nationally by the CTG. From 2006 onwards an increasing part of the hospital budget will be based on negotiated DBCs. To take account of the academic component, academic hospitals will receive an extra budget from 2005 on, financed by the health insurers in proportion to the number of insured[9].

Since the price of a DBC is based on a hospital's costs and the medical specialist's workload, essential in the new financing system is that each DBC has a price per hospital. This price, together with the volume and the content of the DBCs are the stake of negotiations between each hospital, its medical specialists and health insurers. Consequently, hospitals are guaranteed a break-even payment for their activities and medical specialists are paid by performance. The reimbursement system based on DBCs is a fee-for-service system based on a hospital's actual costs[l]. Contrary to traditional fee-for-service systems, incentives for efficiency are stimulated in the negotiations with the insurers.

Medical specialists

The current annual lump-sum system for medical specialists will disappear and be replaced by a DBC-based system of payment. The specialty component of a DBC is a fee based on workload. The uniform hourly rate for medical specialists is determined by the CTG and is based on the time that an activity takes without differentiating between different kinds of activities[m]. A consultation, operation or administrative activity taking just as much time will generate the same remuneration. The main objective of the new remuneration system is to increase the link between payment and work/performance.

Comparison DBC-DRG

Although DBCs are similar to DRGs, there are some important differences between the two case-mix classification systems. In a DBC system the use of a hospital's resources and the workload of the medical specialists are linked to all activities –from the initial examination to the follow-up and rehabilitation services- in the care process. Because DRGs are averages, this direct link with real costs is missing in a DRG system. Also, substitution effects between inpatient and outpatient care are better accommodated in the DBC system. A DRG is essentially a summary mainly of the day case and inpatient components of several DBCs without comprising all the DBC.

3.4.3. Current hospital drugs financing system

In general, hospital drugs are not reimbursed separately, but are financed out of the global hospital budget. In fact, in most hospitals a budget is allotted to the hospital pharmacy to finance drugs, infusion and rinsing fluids, other pharmaceutical products as well as the salaries of the

[k] Each activity is registered with a CTG-code. There are 3037 codes with descriptions of their medical content[7].

[l] All hospital costs are attributed to the CTG-codes. In calculating total costs, a distinction is made between support cost centres ("hulpkostenplaats") and production centres ("hoofdkostenplaats"). The costs of patient related departments are indicated as direct costs and are attributed to the production centres. The costs of non-patient related departments (administration, hotel services…) –the indirect costs- are allocated to the support cost centres.

[m] Only for the 10% activities of the segment B the CTG determines the hourly rate. For 2005 a provisional hourly rate of EUR 140 was advised by the CTG[10].

pharmacists and other pharmacy workers[11,12]. The hospital units bear the financial responsibility for this "budget".

Contrary to the drugs sold in public pharmacies where a maximum price is fixed through European price comparisons, pricing of the hospital drugs is hardly regulated[13,n]. The hospital (pharmacies) or regional purchasing groups freely negotiate the purchase price with the pharmaceutical industries. In general hospitals pay less than public pharmacies. Since hospital drugs are paid out of the overall hospital budget, the discounts can be used to finance other hospital activities.

Until April 1, 2000 drugs purchased by hospital pharmacies were for hospitalised patients only[o]. Since then a change in legislation made it possible for hospital pharmacies to sell drugs to outpatients and for public pharmacists to provide drugs to hospitalised patients[11]. The additional revenues from selling drugs to outpatients are added to the hospital budget.

3.4.4. Future hospital drugs financing system

The budget for hospital drugs will depend on whether the drugs are used in segment A or B. As mentioned before, for segment B the budget is the result of negotiations on DBC prices and volumes between insurers and the hospital. Part of the budget is used to finance drugs. In segment A the current FB system still applies. The only change in this segment is that the hospital budget is based on DBC prices fixed by the CTG.

Steenhoek[14] developed an algorithm to attribute the costs of hospital drugs to the different DBCs. However, due to a lack of detailed cost data, his proposal can not be applied immediately.

3.4.5. Exceptions for expensive drugs[p]

As mentioned before, the yearly budget for hospital drugs is part of the global budget allocated to the hospital (until January 1, 2005). However, in March 2002 a separate policy rule for expensive drugs in hospitals was introduced[q]. Indeed, the percentage the hospital budget spent on new and expensive drugs increased from 6.2% in 1996 to 11.7% in 2000[16]. According to the new rule, a maximum of 75% of the real costs[r] of a selection of expensive drugs is reimbursed on top of the overall hospital budget[s]. The remaining costs are paid out of the overall hospital budget. Each hospital negotiates with the local private health insurers and sickness funds on the principle and the maximum percentage (but not more than 75%) of the reimbursement[t]. This is done for each substance name on the list approved by the CTG. This list is updated yearly.

To qualify for expensive drug reimbursement, a drug has to meet all of following criteria:

a) Costs of the drug

- The costs[u] of the drug by treatment day (inpatient day or day case day) are at least a tenfold of the average cost of all drugs by treatment day;
- Total costs of the drug at the macro-level are a least 0.5% of total costs for all drugs in all hospitals;
- The list of substance names can be enlarged retroactively to the year in which the real costs of a particular substance exceed the 0.5% cost criterion.

b) Budget compensation for a drug

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[n] Except for drugs that are reimbursable (they are on a positive list) when dispensed extramural, even if they are dispensed in a hospital pharmacy. Those drugs are subject to the "Medicinal Product Prices Act" ("Wet Geneesmiddelen Prijzen" – WGP) that fixes a maximum price.

[o] Drugs reserved for hospital use only or drug formulations not readily available in public pharmacies could be provided to outpatients.

[p] This section heavily relies on Beleidsregel I-67015. We do not treat the financing of orphan drugs.

[q] "Beleidsregel dure geneesmiddelen in ziekenhuizen" in Dutch. Before March 2002 special arrangements existed for the reimbursement of Paclitaxel, Docetaxel and Infliximab (for rheumatoid arthritis) because different policies concerning the use of these drugs were noticed between hospitals.

[r] The real costs are estimated on the basis of the Taxe-prices. The Taxe or Z-index is a list of prices set by the producers, satisfying the tariff orders of the CTG (College Tarieven Gezondheidszorg). In fact, the real costs are the costs the hospital actually pays to the deliverer.

[s] « Nacalculatie » in Dutch.

[t] The "Beleidsregel dure geneesmiddelen in ziekenhuizen" is part of the segment A (no free negotiations). At the local level it can be decided to keep the financing of expensive drugs as before, or to integrate their costs in the relevant DBCs.

[u] Costs are calculated on the basis of the cheapest net purchase price after deducting discounts and bonuses.

Expensive drug reimbursement of the costs of a drug is not allowed if the hospital budget is already compensated for this drug:

- For some drugs (e.g. surfactants, retrovirals, dialysis and haemostatica) specific parameters are used to adapt the budget;
- According to articles 2 and 8 of the WBMV (Wet Bijzondere Medische Verrichtingen) some very expensive treatments can be performed only by a limited number of hospitals (treatment centres). For these treatments the selected hospitals get an earmarked budget, including the cost of drugs. For example, the treatment of patients with HIV infections or AIDS is concentrated in about 20 AIDS treatment centres.

c) Rational pharmacotherapy

Rational pharmacotherapy is a prerequisite for expensive drug reimbursement. Rational pharmacotherapy stands for the treatment, prevention or diagnostics of a disease with the drug that has a suitable form for the patient, of which the effectiveness is shown in the scientific literature and which is the most economical for the sickness fund and the patient. Pharmacotherapy is only rational if the therapy is applied to the indication the drug was registered for and if the medical indication is generally accepted. The Commission Pharmaceutical Help of the Health Care Insurance Board ("College voor Zorgverzekeringen" - CVZ) checks this criterion. In case of similar diseases within the registered indications, the evaluation of the cost criterion is based on the total costs of these similar diseases. On the other hand, for different diseases belonging to a specific indication range, the costs are evaluated separately.

d) Regular prescription behaviour in hospitals

The drugs fall within the regular prescription behaviour of hospitals[v].

e) Substitution for cheaper treatment methods

A drug is not eligible for expensive drug reimbursement if this would stimulate the substitution of a relatively cheaper treatment for a much more expensive medicinal alternative[w].

In 2004 the following substance names were eligible for expensive drug reimbursement:

- Docetaxel
- Irinotecan
- Gemcitabine
- Oxaliplatin
- Paclitaxel
- Rituximab
- Infliximab (Crohn's Disease and rheumatoid arthritis)
- Immunoglobine IV
- Trastuzumab
- Botulinetoxine (Local Dystonias)
- Verteporfin
- Doxorubicine liposomal

Between January 1, 2001 and May 1, 2004 a temporary rule of 100% reimbursement applied to Remicade (Infliximab). Since May 1, 2004 the field of application of Infliximab –as an expensive drug- has expanded to rheumatoid arthritis (besides Crohn's Disease) reducing the maximum reimbursement for those patients to 75% of real costs. For patients treated with Infliximab for rheumatoid arthritis up to and including April 30, 2004 the 100% reimbursement continues.

[v] To make the distinction with drugs used in alternative medicine (« reguliere geneesmiddelen » in Dutch).
[w] Only relevant in case of therapeutic identical treatments.

The reimbursement for expensive drugs was intended to avoid the hospital giving too low priority to expensive drugs. However, in practice there may be some problems to satisfy this objective, particularly because the local health insurers can refuse to pay the 75% of costs of expensive drugs[x].

An evaluation of the policy rule expensive drugs in hospitals for the years 2002 and 2003 showed that for both years the volume of the macro budget was comparable. About 26 million EUR was reimbursed to the general hospitals for the total of all substance names on the list, with Remicade costing an extra 20 million EUR a year (100% reimbursement). For the academic hospitals the extra budget amounted to 9 million EUR for the substance names on the list and 6 million EUR for Remicade. With regard to the reimbursement percentage, about two thirds of the general hospitals negotiated the maximum of 75%. For the other general hospitals the percentage lied between 50 and 60%. In all hospitals the same reimbursement rate applied to all accepted substance names. For the academic hospitals the negotiated reimbursement percentages differed more widely: two academic hospitals received 40% of total expensive drugs costs, two others negotiated the maximum rate of 75%.

[x] Another minus is that the pharmaceutical industry increased the price of these drugs (sometimes up to 75%) as a reaction to this rule[17].

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3.5. UNITED KINGDOM[a]

Contrary to the other countries in the overview, the United Kingdom has a national health service (NHS) which is not insurance-based but funded mainly by taxes. The NHS is based on the principle that everyone is entitled to health care free of charge at the point of delivery.

The NHS Plan of July 2000 set out the programme of investments and reforms of the British Government for the next ten years, in order to redress geographical inequalities, improve service standards and extend patient choice[1]. The Plan introduced the most fundamental and far-reaching reforms since the NHS was established in 1948. The NHS financial reforms were announced in a progress report on the NHS Plan -Delivering the NHS Plan[2]. The aim of the new financial system was to pay NHS hospitals (and other providers) on the basis of the work they do. Under the "payment by results" policy hospitals will receive fixed payment - the national tariff- for each type of patient treated[3]. The tariff is based on the average cost for a Healthcare Resource Group (HRC), the equivalent of a DRG. The introduction of the policy is phased over the period 2003-2008. Prior to these reforms the operating costs of NHS hospitals were determined by the contracts negotiated with purchasers of certain services.

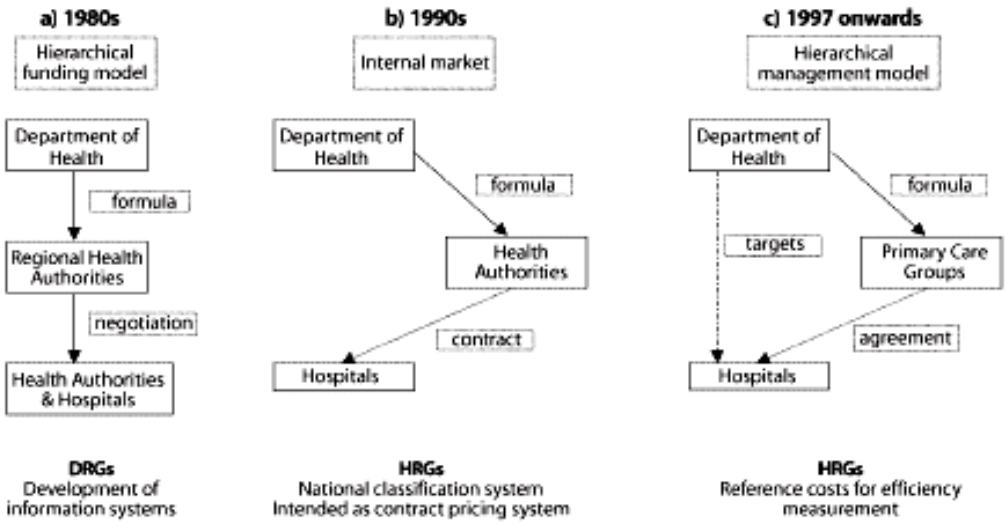
We first describe reforms of hospital financing and the financial flows from the regional authorities to the hospitals before the introduction of the "payment by results". Next, we give an overview of the different phases to be introduced in the payment by results scheme, and the way the prospective tariff is determined. The reimbursement of hospital drugs is described in sections 3.5.3 and 3.5.4 for the old and newly introduced system respectively. The financing of expensive hospital drugs is discussed in section 3.5.5.

3.5.1. Previous system of hospital contracts (1991-2003)

Hospitals

The majority of acute care in England is provided by the public sector (NHS). About one-tenth of acute care beds are available in private voluntary and for-profit hospitals. Since its introduction in 1948, the NHS was reformed many times. The broad lines of the reforms influencing NHS hospital structure and hospital funding, can be summarized as in figure 1[4]. The most radical reform was on April 1, 1991 (NHS and Community Care Act of 1990)[5] with the introduction of an internal market for health care based on a system of contracting for services between purchasers and providers.

Figure 1: Structure of the NHS and hospital funding



[a] Although many features are the same for all UK countries, we focus on England.

During the eighties the NHS was organised on hierarchical lines. The NHS payments to the public hospitals, made by the Department of Health (DoH), passed through the regional and district health authorities (RHA and DHA) who were responsible for providing and paying for hospital services. Funds from the DoH were allocated to the 14 RHA on the basis of a needs-based capitation formula. The flow of funds from the RHA to the DHA and from the DHA to the hospitals was the result of local negotiations. Hospitals funded their operating costs through prospectively determined global budgets by their DHA, based mainly on historical costs.

The first major reforms of the NHS were announced in the government's White Paper (1989) "Working for Patients" and passed into law as the NHS and Community Care Act (1990), which came into force on April 1, 1991. The reforms with respect to the hospital sector include the introduction of an internal market for hospital services separating the responsibility for purchasing and providing health care and the establishment of NHS Trust hospitals[b].

Since 1991 each hospital's budget is determined by the contracts it negotiates with different purchasers for specific services[5].

Three main types of NHS contracts between the health authorities and NHS trusts were introduced by the internal market reforms:

- Block contracts: the provider receives a fixed monthly payment for the supply of services for the local population. The concrete numbers and types of cases treated under the block contract are not set, but upper and lower limits may be determined. Block contracts were used mainly by DHA to purchase services from their main providers.
- Cost and volume contracts: the provider receives a fixed payment for a basic level of treatment and extra payment on a cost per case basis for treating patients beyond that basic level. These contracts usually were smaller contracts.
- Cost per case contracts: the provider receives an agreed price for each case treated. They were often used for small volume/high cost specialist treatments.

Health Authorities were encouraged to use block contracts because they created the least uncertainty while the largest amount of risk was passed on to the provider. But the purchasers had little control over what they were getting for their payments. Standard contracts related to the next fiscal year, but longer term contracts became more and more common over time. Also, contracts increasingly specified detailed service requirements or workload measures. But most contracts between HA and hospitals remained specified in rather broad terms for total activity. Since hospitals were hardly funded on the basis of their casemix adjusted activity, the development and application of a casemix classification system lagged behind most other countries. Although a measure of hospital casemix activity can be traced back to the early 1980s, it was only in the late 1990s that hospitals were forced to collect cost information of individual treatments[4]. The Health Resource Groups (HRGs) were the UK equivalent of the DRGs used in the United States. Since 1997 HRG costs have been published for all English hospitals and are referred to as reference costs. Until recently, HRGs were not used for reimbursing hospitals but mainly for benchmarking exercises such as the use of HRG costs to set hospital efficiency targets. However, reference costs were introduced as part of far-reaching reforms of the NHS structure (see part c in figure 1) replacing the HA by Primary Care Groups (PCGs) and Primary Care Trusts (PCTs) in purchasing health care.

This locally determined funding for hospital treatments through contracts has been applied until now. Summing up, the NHS contract system can be described as a mixed reimbursement system with global budgets and some elements of cost per case payments. One of the major problems of this reimbursement system was that the NHS was under-funded for years. This permanent under investment was the prime cause of increasing waiting lists and waiting times. The change to a payment by results system should be seen against this background.

[b] Another major reform for the outpatient sector was the introduction of general practitioner fundholding.

Specialists

Hospital doctors (or consultants) are directly employed by the NHS hospital on a salaried basis[6]. However, the consultants have the choice of taking a full-time or a part-time position. In both cases they are allowed to perform also private sector activities. For full-time consultants the private practice is limited to 10% of their gross income. Part-time consultants are allowed to perform an unlimited amount of private sector services without any restriction on their earnings. Consultations in the private sector are paid fee-for-service. Salary scales in the NHS hospitals are negotiated on a national basis. The contracts of the consultants are held by RHA (now PCTs).

3.5.2. The current system of 'payment by results'

The NHS Plan of July 2000 sets the Government's programme of investments and reforms for a ten-year period. It outlines a new delivery system for the NHS as well as changes for patients, changes for doctors, nurses, therapists and other NHS staff and changes in the relationship between the NHS and the private sector.

In a progress report on the NHS Plan, "Delivering the NHS Plan (April 2002)", the next steps of the programme of NHS financial reforms were set out. The report followed a Budget announcing increased spending on the NHS through general taxation: an annual average increase in NHS funding in England of 7.4% above inflation for the five years 2003/04 to 2007/08. A central element of the reforms of the supply side concerned the introduction of stronger incentives for the providers to make sure that the extra money also produced improved performance.

In the progress report it was announced that the flow of funds through the system had to change fundamentally. The hospital payment system had to switch from commissioning through block contracts to "payment by results" so that hospitals would be paid for the activity they undertake. The general idea was that PCTs[c] would "commission the volume of activity required to deliver service priorities from a plurality of providers on the basis of a standard national price tariff, adjusted for case mix and for regional variation in wages and other costs of service delivery"[7]. The key principle of the payment by results system is that providers are contracted for a minimum volume of cases to achieve waiting time reductions. In case of failure to deliver this minimum they will lose money on a cost per case basis; when additional patients make use of their services, they will earn extra money also on a cost per case basis. So increases or reductions in activity will be charged at full, not marginal, cost. Since the experience of the internal market had made clear that price competition did not work, the Health Resource Group (HRG) was proposed to be the benchmark for a standard tariff to pay the same amount of money for the same treatment regardless of provider. The standard national tariff is meant to be an incentive for NHS Trusts to manage costs efficiently. The commissioning agreements between PCTs and providers are called the Service Level Agreements (SLAs)[d].

The move to a full system of payment by results and a nationally agreed set of prices for the HRGs was phased in over the years 2003/2004 to 2007/2008. We briefly go through the most relevant changes in the different phases[7,8].

In the transition to a standard national price tariff for 2005/06, a minimum activity was covered in the first phase 2003/04. For six selected key surgical specialties, SLAs based on casemix adjusted volumes were set at specialty level. The six specialties are: general surgery, urology, trauma and orthopaedics, ENT ('ear-nose-throat'), ophthalmology and cardiothoracic surgery. Prices in these SLAs were not determined by the national tariff, but they were determined locally. However, the weight used to casemix adjust the volume of activity was based on national average reference costs. In addition, for 15 strategically important procedures, commissioners were required to pay for extra activity (above last years planned levels) at a predetermined national tariff. For 2004/05 the same methods and principles as in the first period hold, but the number of individual HRGs is extended to 48. From 2005/06 case-mix adjusted cost and volume commissioning will be applied to most or all medical and surgical specialties and also outpatient activities. Local negotiation of prices will be reduced and a transition path to the national tariff will be mandated. From April 2005 there will be a full roll out of the national tariff.

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[c] PCTs receive budgets directly from the Department of Health. Since April 2002, PCTs have taken control of local health care while 28 new Strategic Health Authorities monitor performance and standards.

[d] Payment by results – the way the money flows through the system- was only one tool of the commissioning activities of the PCTs. Other tools can be found in Annex 5 of [7].

The tariff for 2005/06 will cover admitted patient care (day-cases, elective and non-elective in-patients), outpatients and accident and emergency services. For each HRG there are two tariffs: one for an elective spell and one for a non-elective spell. A supplementary payment will be made for outliers[9].

3.5.3. Financing hospital drugs in the previous system

Hospital drugs were (and still largely are for the time being) paid for through the contracts between the DRA or PCTs and the hospital.

The costs of the hospital pharmacy service and hospital drugs are financed from the overall allocation to the NHS hospital[10]. The Chief Pharmacist receives and manages the budget for the pharmacy service, whereas the budget for drugs is usually delegated to clinical directorates. Trust management hoped that allocating the drug budget to directorates would lead to more cost-effective prescribing.

In October 1991 the NHS Supplies Authority was established. This agency was responsible for NHS supplies. All purchases were intended to occur through the best priced local source except when bulk purchases could realize major savings.

The prices of drugs bought by hospitals or Trusts are determined by negotiation. In some instances this is done by the pharmaceutical company and the hospital pharmaceutical-purchasing manager or by the NHS Supplies Authority on behalf of the hospital. Deals are normally based on bulk purchase.

3.5.4. Financing hospital drugs in the new payment by results/HRG system

In general the cost of hospital drugs is included in the standard tariff for each HRG.

3.5.5. Expensive drugs and other exceptions for drugs in the new system

One of the principles of costing to be applied in the NHS, mentioned in the NHS Costing Manual, is that the costs of services should be calculated on a full absorption basis, i.e. inclusive of all the costs associated with the delivery of these services[11].

This means that all drugs, high cost or otherwise, are incorporated in the HRG prices. However, an exception was made for "chemotherapy and associated drugs" on the following ground (for the period 2003/04): (1) HRGs were only available for drugs for solid tumours and not for other cancers which makes the coverage of these services by HRGs partial and incomplete and (2) aspects of chemotherapy were included in the inpatient and day case HRGs but a revision of them is not possible for the moment which makes it not feasible to calculate the cost on a full absorption basis for the provision and reimbursement of chemotherapy based treatments.

From the 1st of April 2005 the national tariff in the payment by results system will cover about 70% of income. Compared to the experimental phase, some changes have been made relevant for the financing of expensive drugs. The following high cost drugs will not be covered by the mandatory tariff[9,e]:

- AIDS/HIV Antiretrovirals
- Anti-TNF drugs
- Beta interferon
- Betaine
- Carnitine
- Cysteamine
- Enzyme replacement therapy
- Hepatitis C drugs
- Intravenous/sub-cutaneous human normal immunoglobulins

[e] Similarly, the outpatient tariff excludes these high cost drugs.

- Palivizumab
- Pulmonary Hypertension drugs
- Riluzole
- Sodium phenylbutyrate
- Somatropin
- Verteporfin

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3.6. CANADA – ONTARIO

Hospitals in Ontario are financed through a global budget. An alternative funding method, based on case-mix, is currently discussed. To understand the reasons of this proposal, we first give an overview of the characteristics of the current model. Then we describe the reform planned. In the next sections, we describe the reimbursement of hospital drugs and the exceptions observed.

3.6.1. Current hospital financing system

Ontario has four different hospital types including public hospitals, private hospitals, federal hospitals, and Cancer Care Ontario Hospitals, but the public type of hospitals is the main observed.

Public hospitals are financed by The Ministry of Health and Long-Term Care (MOHLTC) through

- global funding for the majority of in-patient and out-patient programs;
- priority funding for special programs such as dialysis, hip and knee replacement and organ transplants;
- one-time funding based upon political decision or other criteria; and
- separate funding for capital construction projects.

The largest portion of hospital's funding comes through the global budget[1,2].

The global budget covers hospital's operating costs except medical fees. Physicians are paid for the services they provide through fee-for-service arrangements, with remuneration based on the Schedule of Benefits. MOHLTC negotiates payment rates and other changes to the Schedule of Benefits with the Ontario Medical Association[3]. However, in some hospitals, physicians are funded out of the global budget under an "alternative funding payment" (salary or block funding).

Historically the hospital budget has been based upon past allocations, yearly economic increases and a hospital's ability to negotiate funds with the MOHLTC. The result was that the hospital sector evidenced inequities in funding.

Over the past years, the Joint Policy and Planning Committee (JPPC), a partnership between the Ministry of health and the Ontario Hospital Association (OHA), has developed a hospital funding formula to improve equity in the financing system. The goal of the formula is to ensure that each hospital is able to provide an equal share of appropriate services to its population, given the annual hospital budget in Ontario. The Ministry of Health and Long Term Care determines each year the amount of money to be applied under the formula whether that be new funding or a part of the global budget[1].

There are two parts in the JPPC formula. The Volumes Model attempts to estimate how many cases a hospital should treat in a given year. The Rates Model attempts to estimate the hospital's cost for treating each case.

The Volumes Model predicts the volume of care expected for each region of Ontario, given population characteristics and according to the average Ontario rate of utilization. Population characteristics used in predicting the volume of care include age, sex, rural location, income, mortality, aboriginal population and fertility. This model then calculates the market share each hospital has in each region and allocates these volumes back to the hospitals. Hospital's actual volume performances are then measured against their expected volumes. If actual volume is less than expected, the community is "under-provided" and the hospital will receive a larger share of money. The objective is to ensure that the funding of hospitals is proportional to each population's expected volume given the referral population's unique characteristics[1].

Patient volumes are measured using "weighted cases". The Canadian Institute for Health Information (CIHI) collects financial and clinical data from some Ontario and Alberta hospitals (21 hospitals in Ontario[a]). CIHI then processes and groups each acute care patient record into a single Case-mix group (CMG). Each CMG is further divided into sub-categories according to severity and complexity and each sub-category has an associated Resource Intensity Weight

[a] Collection of data is not compulsory. Interested hospitals can apply to participate to the "Ontario Case Costing Initiative", a project launched in order to develop a reliable case weighted system.

(RIW). The volume of weighted cases is calculated by multiplying the RIW by the volume of each sub-category[4].

The Rates Model calculates the expected cost per unit of output with a statistical model that uses actual cost data from a group of hospitals, adjusted for hospital size, degree of tertiary care provided and teaching activity, isolation status and proportion of chronic care provided. These factors can lead to differences in costs that are beyond the hospital's control and are not reflected in the case-mix measure. Expected costs are then compared to actual costs per weighted cases. If actual costs are less than expected, the hospital is rewarded with a larger share of money. The rate model is thus an incentive for hospital to reduce their actual cost per unit[4].

Rate and Volume Models have been developed separately, but the results are multiplied together in order to define a hospital's performance ranking:

expected costs per units x expected volumes = expected total cost

Hospitals that have actual total costs less than expected have a greater chance of receiving more money. Government may decide only to fund hospitals that are well below their expected costs and not just a little below.

The formula was first applied in 2001 to distribute an additional lump sum to hospitals. It was planned to use the formula for the allocation of a larger portion of the hospital budget, but it still being only applied for marginal increases of the budget.

The amount of money for priority programs, which are often programs with high costs, high variation in costs and low volumes, is not distributed on the basis of the JPPC formula but on the basis of the volumes of cases treated by hospitals.

Cancer Care Ontario hospitals are also funded through the global budget and by the funds of Cancer Care Ontario, a provincial agency financed by the MOHLTC[5].

Problems with the current system:

Use of the volume model as a planning system

The intention of the Volume Model is to shift resources from well provided to under-provided communities. In practice, the use of a formula to shift resources between hospitals, instead of employing a proper planned approach, can lead to unintended results. Higher or lower than average services levels may only occur for specific types of services. A hospital providing less than average levels in certain areas will receive more funds but may not necessarily use those funds to provide the services needed. The volume model also assumes that hospitals have more control over their volumes than may be actually the case[4].

Unclear incentives

Combining the cost per unit and volume performance results can lead to an ambiguous global result and thus to an ambiguous incentive. If a hospital performs poorly under the rate formula but very well under the volume formula, its global result can be positive.

Complexity of the methodology

Furthermore, hospitals have difficulties in knowing precisely how to respond to improve their funding prospects. They are in a race with each other, but they are unable to observe the position of their competitor, due to the lack of information and the complexity of the formula. Thus they don't know how low they need to drive down their costs to be in a better position than the others.

3.6.2. Future hospital payment system[4]

Use of the JPPC formula was planned to be extended to the distribution of the whole hospital's global budget in the following years. However, Ontario's government has recently (September 2004) announced that a regional structure may be imposed in Ontario. This may entail population-based regional funding although the details are unknown at this point in time.

Several recommendations about alternative funding methods have been made by the Standing Senate Committee on Social Affairs, Science and Technology and by the Ontario Hospital Association.

The reform proposed is to finance hospitals on the basis of the number and type of services that they actually deliver.

An average base rate for each case-mix group would be calculated on the basis of clinical and financial data collected by the Canadian Institute for Health Information. This average base rate would be adjusted in accordance to factors as hospital size, degree of tertiary care provided and teaching activity, isolation status and proportion of chronic care provided. Simultaneously, planned volumes would be estimated for overall services and specified sub-categories, for a period such as three years. These planned volumes would be negotiated between the hospitals and the government.

A hospital's (three year) budget would then be the product of the rate and the negotiated volume.

This system would promote greater stability and predictability of the funding. The base rate as a standard would be a clear target and an incentive to promote efficiency (only those hospitals that can provide service for the base rate will do so).

3.6.3. Current hospital drugs financing system

In Canada, all drugs administered to patients in hospitals, or intravenous drugs given in the outpatient departments of hospitals or ambulatory care centres, are provided free to patients as an insured service in Canada's publicly funded universal access health care system. Therefore, it's not possible to bill inpatients or their third party insurance provider for the cost of these drugs[6].

Hospital drugs are paid for through the global budgets of hospitals or through dedicated cancer centres.

3.6.4. Future hospital drugs financing system

The cost of hospital drugs would be integrated into the calculation of the standard base rates per case-mix groups.

3.6.5. Hospital drugs financing system: exceptions[6]

Until recently, the availability of new expensive drugs into a particular hospital was dependent on whether the hospital could accommodate the additional cost of the drug in its operating budget. This led to an unequal access to new expensive drugs.

Cancer Care Ontario (CCO), a provincial agency established to integrate and coordinate cancer services in Ontario, decided in 1994 to fund a chemotherapy drug, paclitaxel (Taxol™), from its own reserve, in order to ensure equitable access to this drug. Simultaneously, the Cancer Care Ontario's Practice Guidelines Initiative was established. This initiative coordinates the development of clinical practice guidelines in Ontario using systematic literature.

Cancer Care proposed in 1995 to the Provincial Government that paclitaxel be funded by the Ministry of Health according to the guidelines (hospitals were reimbursed only for paclitaxel administered to eligible patients according to guidelines).

Based on the success of this funding program, the MOHLTC established a provincial New Drug Funding Program in 1997. This program funds new intravenous anticancer drugs on the basis of recommendations made by the Policy Advisory Committee. This committee reviews the evidence in practice guidelines received from the Practice Guidelines Initiative. Economic impact analyses, based on an estimate of the total population of patients who might benefit from the new drugs, are simultaneously conducted.

In 2001, the New Drug Funding Program included 14 drugs.

Drugs included in the New Drug Funding Program[6]

Drug	Indication
1. Clodronate	Metastatic breast ca
2. Docetaxel	Metastatic breast ca, 2nd line non-small cell lung ca
3. Epirubicin	Metastatic breast ca
4. Gemcitabine	Pancreatic ca, non-small cell lung ca
5. Interferon	Melanoma
6. Irinotecan	1st and 2nd line metastatic colorectal ca
7. Liposomal anthracycline	HIV positive Kaposi's sarcoma
8. Paclitaxel	Metastatic breast ca, 1st/2nd/3rd line ovarian ca
9. Pamidronate	Plasma cell myeloma, Metastatic breast ca
10. Raltitrexed	Metastatic colorectal ca
11. Rituximab	Non-Hodgkin's lymphoma
12. Topotecan	Advanced ovarian ca
13. Trastuzumab	Metastatic breast ca
14. Vinorelbine	Metastatic breast ca, non-small cell lung ca

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3.7. CANADA – QUEBEC

Hospitals in Quebec are currently financed through a global budget. A reform is planned in order to base the allocation of the budget on the volume and the costs of cases treated by each hospital.

3.7.1. Current hospital financing system

Quebec has three different hospital types including public hospitals, private non-profit hospitals, and private for-profit hospital.

Public hospitals are financed by the Ministry of Health and Social Services ("Ministère de la Santé et des Services Sociaux" – MSSS), as well as private non-profit hospitals which have signed an agreement with the Ministry. Private for-profit hospitals are not publicly financed[1].

The MSSS determines every year a global budget for the hospitals operating costs, on the basis of previous indexed global budgets.

This global budget is then divided between the regions. According to the Health Services and Social Services Law (« Loi sur les services de santé et les services sociaux »), the sharing out of the budget should be based on regional population needs to ensure equity in the distribution of resources. However, this principle has only been partially applied in the years 1995-1996 and 1997-1998, a period of rationalisation of the Quebec's health network, characterized by multiple hospitals merging and a reallocation of resources. In other periods, the distribution of the global budget has been principally based on historical budgets of the regions[2].

Once the regional budget has been decided, the regional health agencies ("Agences de développement de réseaux locaux de services de santé et de services sociaux") distribute it among hospitals. There is no explicit rule about the methodology to be employed but the agencies must submit their plan to the Ministry of Health and Social Services.

The distribution of the regional budget among hospitals mainly takes into account historical allocations. Adjustments have been made by some large regional agencies (Montreal, Québec, Laval) on the basis of hospital efficiency or on the basis of reorganization programs (shift to ambulatory care, merging of services)[1]. Four agencies (Gaspésie-Îles de la Madeleine, Chaudières-Appalaches, Estrie and Mauricie-Centre du Québec) have tried to finance their hospitals according to a normative approach of the hospital needs. Financial needs of hospitals have been calculated on the basis of population needs and unit costs. The application of this methodology has been limited by lack of information about the parameters utilized[2].

Medical fees are not included in the hospital global budget. Physicians are paid by the health insurance authority ("Régie de l'Assurance Maladie du Québec" – RAMQ) on the basis of a fee-for-service schedule. A specific budget is determined each year for medical fees, which cannot be exceeded[3].

Investment costs are not included in the global budget but are financed by the Ministry of Health and Social Services on the basis of propositions made by the regional agencies. Agencies submit each year to the Ministry a list of investment projects, with their costs and a priority degree[1].

Problems with the current system

There is little relation between the level of hospital activity or productivity and the level of hospital financing. Therefore it provides little incentives for efficiency. This could lead to recursive over-financing or rationing.

3.7.2. Future hospital payment system[2]

In June 2000, the Ministry of Health asked a committee[hhh] to revise the methodology used for the allocation of the regional budgets to hospitals. The objective was to link the hospital budget to the volume and severity of cases treated and to the hospital performance.

The committee proposed to base the allocation of the regional budget on the volume and the expected cost of weighted cases.

Clinical discharge data of hospitals are collected through an information system named "MED-ECHO" based on ICD-9 codes for diagnoses. Each patient record is processed into a single case-mix group. The classification system utilized is the AP-DRG system. Each AP-DRG has an associated resource intensity weight ("Niveau d'Intensité Relative des Ressources Utilisées" - NIRRU). As there is no information about Quebec hospital costs, weights are calculated on the basis of data from Maryland (U.S.A), with some adjustments, mainly for the length of stay.

For each hospital, the expected cost of cases would be calculated on the basis of an econometric model with four explicative variables: the NIRRU, the hospital teaching activity (relative number of interns), the rural location and the number of tertiary neonatology cases.

The expected budget, on which the allocation of the regional should be based, would then be the product of the volume and the expected cost of weighted cases.

Until now, this principle has only been applied to some marginal adjustments of the allocation of the global budget, but there are plans to extend it to a larger share of the global budget.

3.7.3. Current hospital drugs financing system

Hospital drugs are financed through the hospital global budget. They are no exceptions.

3.7.4. Future hospital drugs financing system

With the methodology proposed by the Bedard committee, the cost of hospital drugs should be integrated into the calculation of expected cost by AP-DRG.

[hhh] The committee was leaded by Denis Bédard and included members from the MSSS, from the Quebec hospital association ("Association des Hôpitaux du Québec") – AHQ, from hospitals and from the regional agencies.

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4. GENERAL CONCLUSIONS AND DISCUSSION

Two main types of financing systems appear from our survey:

- A global hospital budget system with attempts to base its allocation on regional needs and on hospital efficiency, and no longer on historical expenses. This is the current system in most of the surveyed countries.
- A move towards an "all-in" case-mix payment (per diagnosis based group) with generally special separate provisions to pay for a limited number of expensive drugs. Some countries are in the process of implementing this type of reform, while other countries are in a stage of planning.

Comparable classification systems are used for the grouping of diagnoses: AP-DRG in Switzerland and Quebec, AR-DRG in Germany, GHS in France, HRG in the United Kingdom, DBC in The Netherlands and CMG in Ontario.

The "all-in" case-mix system has the advantage of promoting efficiency by basing reimbursement on average costs per pathology and permitting substitution between various components of the cost of care (for example, if drugs expenses are really high for a case, other fees can be lowered and vice-versa) and between patients with different degrees of severity and different related costs. The chance to exceed the average cost for a specific pathology is lower in an "all-in" system than in a restricted application of the case–mix system for only one or a few categories of expenses (like a diagnosis-based or lump-sum system for hospital drugs only).

Therefore diagnosis-based systems appearing in our survey cover drugs as well as care expenses and medical fees. The only exception observed is in French private hospitals, where medical fees are not included in the lump sums per pathology. Some countries like The Netherlands and the United Kingdom go even further and attempt to include also outpatient hospital care. The diagnosis-based systems are introduced for a number of reasons (like increase in efficiency of the hospital system, decrease of waiting lists or health care cost-containment) in function of the country specific situation and previous financing systems. In most cases the introduction of the diagnosis-based financing system is gradual, phased in over several years.

Expensive and innovative drugs exert a pressure on the hospital (pharmacy) budget level or on the allotted amount at the specific diagnosis-based level. Therefore some adaptations of the budget or of the reimbursement level per pathology have been introduced in France, Germany, The Netherlands, the UK and Ontario. Exceptions in the hospital drugs financing systems cover mainly coagulation factors for haemophiliacs, human immunoglobulins, anti-cancer drugs as Trastuzumab, Rituximab, Docetaxel, Gemcitabine, Irinotecan, Paclitaxel, and drugs for rheumatoid arthritis as Infliximab. Lists of exceptions are however determined on the basis of different criteria in each country: very high cost compared to the average (France, The Netherlands), cost-efficiency (The Netherlands, Ontario), high variability of cost in a diagnosis based group (France), and conformity with guidelines (Ontario). Hence, in practice the exceptions relate to the field of haematology/oncology or immunomodulation treatments.

In most diagnosis-based systems special allowances are also made for outliers i.e. hospital admissions with very high costs.

Belgium is the only country to restrict the use of a case-mix system to the financing of specific hospital expenses in surgery. An "all-in" case-mix system permits substitution between the various components of the cost of care and within a sufficiently large group of often heterogeneous cases. A "restricted" case-mix system does not incorporate these advantages. A necessary precondition is that the "all-in" hospital budget is sufficient to provide appropriate patient care.

Further points that should receive attention are the amount and impact of discounts of purchases by hospital pharmacies, the ability of hospital to "resell" drugs to outpatients and competition law issues raised by the new EC Public Procurement Directive and the EU Competition Law.

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