

Payment Policies and Hospital Decision-making Concerning the use of Coronary Stents: The Importance of Reimbursement Measures in Germany

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Introduction

Coronary heart disease (CHD) is one of the major causes of death in the European Union. However, its mortality rates are falling steadily in western European countries.¹ CHD is a clinical area in which (innovative) technology plays an important role. The introduction of coronary stents has been one of the most important advancements in the percutaneous treatment of coronary artery disease – the most common cause of CHD – since the late 1980s. The development of stent technologies involves a wide range of products that take hospital decision-making into consideration. The choice of technologies for cardiologists ranges from bare-metal stents (BMS) and drug-eluting stents (DES) to newer stents, such as coated or bifurcation stents.²

Market access for medical devices, such as stents, is regulated through European Union directives, which have been transposed into national law. The CE mark is the permission of manufacturers to market their medical devices in all EU member states, yet coverage and reimbursement decisions are regulated at the national level. These components have an impact on the adoption and use of technologies.³ In Germany, medical devices are almost always first introduced in the inpatient sector because hospitals may employ any technology that has not been explicitly excluded by the Federal Joint Committee (G-BA). However, the introduction of the German Diagnosis-Related Group (G-DRG) system in 2004 has placed certain financial constraints on the choice of medical technologies. A technology may therefore be

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used less frequently if it is not appropriately accounted for in the regular system of G-DRG payments.⁴

The present study focuses on coronary stent technologies. It aims to structure payment mechanisms within the G-DRG system and mechanisms for facilitating the uptake of new technologies in the German system of hospital reimbursement. For this purpose data on relevant procedure codes and supplementary payments for coronary stents were obtained from the following regulatory bodies: (1) the Institute for the Hospital Remuneration System (InEK) and (2) the German Institute of Medical Documentation and Information (DIMDI).

German Hospital Reimbursement of Coronary Stents Regular System of G-DRG Payments & Procedure Classification

The German hospital payment system is based on case fees, which are determined by diagnosis-related groups. These case fee payments, which are updated annually, establish a fundamental framework for the reimbursement of technologies.⁵ The main criteria for the classification of patients into DRGs are diagnoses and procedures. For each DRG, hospitals are reimbursed based on its predetermined relative weights (multiplied by the base rate), which includes average personnel, material, and certain infrastructure costs. Each relative weight is calculated by the Institute for the Hospital Remuneration System (InEK) according to (cost) data documented by a sample of hospitals. For medical devices, such as coronary stents, the average costs are determined using the actual purchasing costs of the hospitals. Nonetheless, the average costs used for the calculation of relative weights result from prices negotiated freely between manufacturers and hospitals.⁷⁻⁸

DRG payments received by hospitals remain constant regardless of whether they have implanted a BMS, a DES, or no stent at all. From an economic perspective, hospitals have little incentive to use more expensive stent technologies. To address this problem, supplementary payments may be made in addition to DRG reimbursement (i.e. if a certain procedure does not justify creating a unique DRG, supplementary payments may be made in addition

	2004	2005	2006	2007	2008	2009	2010	2011
8-837.k* Bare-metal stents	X	X	X	X	X	X	X	X
8-837.m* Drug-eluting stents	X	X	X	X	X**	X**	X**	X**
8-837.n Radioactive stents	-	X*	X	X	-	-	-	-
8-837.p Non-drug-eluting covered stents	-	X	X	X	X	X	X	X
8-837.u Non-drug-eluting bifurcation stents	-	-	-	X	X	X	X	X
8-837.v Drug-eluting bifurcation stents	-	-	-	X**	X**	X**	X**	X**
8-837.w* Coated stents	-	-	-	-	X	X***	X***	X***

Table 1. Procedure codes created for coronary stents between 2004 and 2011.

* Additional information on the total number of stents and affected arteries is coded using an extra digit.

** Additional information on the type of drug is coded using the code 8-83b.0, which has 12 different sub-codes.

*** Additional information on the type of coating is coded using the code 8-83b.e, which has 3 different sub-codes.

Source: Authors' compilation based on information from the procedure classifications from 2004 through 2011.¹¹

to DRG payments). The regular system of G-DRG reimbursement includes two types of supplementary payments tabulated in the appendices of the DRG classification. Fixed supplementary payments, whose amount is predetermined and consistent throughout Germany, can be calculated properly only if the new technology has been used for a sufficient number of patients (i.e. generally 250 individuals) and variations in the calculated costs are not too great. If sufficient cost data is not available, negotiable supplementary payments, whose amount is determined at the local level in negotiations between individual hospitals and sickness funds, are used for reimbursement. Both fixed and negotiable supplementary payments are, as DRG payments, calculated as part of a hospital's annual budget.

A new technology can be included in the regular system of G-DRG reimbursement only if it has been assigned a procedure code. Therefore, a standardised coding system – the German Procedure Classification (OPS) – is used to describe specific items and services delivered by providers of inpatient care. Specific procedure codes for technologies are (1) essential when calculating the relative weights for DRGs, and (2) designed for facilitating quality assurance and the uptake of new technologies. Like DRGs, procedure codes are updated each year.

Due to the fact that both the G-DRG classification and reimbursement rates are based on data collected two years previously and considering a financing gap exists for cost-increasing technological innovations, the system produces outdated data. This may represent a particular hurdle for the uptake of new technologies, which therefore can create disincentives for hospitals to adopt and use cost-increasing innovative technologies. Furthermore, a time-lag is already created due to the application process of procedure codes. To bridge this gap in the financing of new technologies, the so-called NUB (New Diagnostic and Treatment Methods) Regulation, which may provide extra-budgetary,

non-DRG payments for hospitals, was introduced in 2005. A hospital wishing to employ a new medical technology must apply to the InEK for permission to enter into contractual negotiations with the sickness funds for extra-budgetary payments. The application must include, *inter alia*, a description of the new technology, specifying the features that make it beneficial to patients, and the reason why the costs of the new technology are not appropriately covered by the current G-DRG system. The technology does not need to have a procedure code.⁹⁻¹⁰

Development of Coronary Stent Procedure Codes

Table 1 shows the range of stent technology procedure codes created between 2004 and 2011. Data were obtained from the procedure classifications published during this period and provided by the DIMDI.

German procedure classification did not account for different stent technologies before the introduction of the G-DRG system in 2004. In 2004, codes distinguishing between BMS and DES were created for the first time. Different codes for various coronary stent technologies have been created since that time, some of which are subdivided depending on the number of stents and arteries. Since 2007, the pharmaceuticals used in the various drug-eluting stents have been clearly identified by using additional code groups and as of 2009, the type of coating used in coated stents has been identified using additional code groups. In 2008, the procedure code for radioactive stents was removed from the procedure classification.

Integration of Coronary Stent Technologies in the Regular System of G-DRG Reimbursement

Figure 1 shows the development of different stent technologies in terms of their integration in the G-DRG system. The vertical fields of Figure 1 represent the different preconditions that must be fulfilled to reach a certain level of G-DRG integration. The three columns to the

right are defined as an “explicit inclusion” in the regular system of G-DRG reimbursement, which implies that a technology is reimbursed through negotiable supplementary payments, fixed supplementary payments, or as a unique DRG.

Since the introduction of the NUB Regulation, three types of stent technologies have been reimbursed according to the NUB Regulation: (1) non-drug-eluting bifurcation stents, (2) drug-eluting bifurcation stents, and (3) antibody-coated stents. With the exception of drug-eluting bifurcation stents, these technologies were reimbursed for one year according to the NUB Regulation without being assigned a procedure code. After receiving a procedure code in 2007, antibody-coated stents continued to be reimbursed in this manner from 2008 to 2011. This technology has not yet been included explicitly in the regular system of G-DRG reimbursement.

Supplementary payments for DES were first included in the 2004 version of the G-DRG classification in terms of negotiable supplementary payments (i.e. their amount was determined at the local level in negotiations between individual hospitals and the sickness funds). This changed with the 2009 G-DRG classification, when these supplementary payments were fixed. For each DES implanted in a patient, a hospital was reimbursed in the amount of €693.11 (EUR) using supplementary payment in 2009. A hospital was reimbursed for a total of six stents per case, resulting in a maximum supplementary payment of €4158.66 (EUR) in 2009. From 2009 to 2011, this supplementary payment continuously decreased by 33%.

The system of regular G-DRG reimbursement thus implies that DES are associated with additional resource consumption, justifying

supplementary payments on top of existing DRG payments. In other words, BMS have become so inexpensive that they do not lead to noticeable additional cost. As such, a DRG payment for a PCI includes the cost of implanting a bare-metal stent, even though the DRG does not make any explicit mention of stenting. This is referred to in everyday practice as “implicit inclusion” in the regular system of G-DRG reimbursement, i.e. BMS have been included implicitly, whereas DES have been included explicitly, in the regular system of G-DRG reimbursement. Further technologies had been explicitly included in the regular system of G-DRG-reimbursement: negotiable supplementary payments for (1) radioactive stents in the 2005 and (2) drug-eluting bifurcation stents in the 2007 and 2008 versions of the G-DRG classification. Since 2011, non-drug-eluting bifurcation stents have been implicitly included in the G-DRG system (i.e. the costs of this technology are appropriately covered by the current G-DRG system). The implantation of one non-drug-eluting bifurcation stent is analogously coded as the implantation of a minimum of two BMS.

Discussion

The prospective G-DRG system faces the problem of bridging the financial gap between the introduction of cost-increasing new stent technologies and its inclusion in the regular system of reimbursement. Until the reimbursement system is updated to account for the extra costs, disincentives for hospitals to introduce cost-increasing innovative technologies should be lessened or prevented by introducing the instrument of the NUB Regulation. Indeed, hospitals have successfully applied for permission to negotiate with the sickness funds for NUB reimbursement for three stent technologies. The disadvantage to the NUB Regulation is that only those hospitals that have successfully applied for permission to negotiate NUB reimbursement may actually

		Extrabudgetary Payments	Add-on Payments	Unique DRG
		Local Negotiations		Pre-determined and Consistent throughout Germany
		NUB Regulations	Included in Regular System of G-DRG Reimbursement	
With Procedure Code	High Number of Treated Patients and Low Cost Variation			Fixed Supplementary Payment Drug-eluting 2009-2011
	Number of Patients Treated using the Technology is too Low, or Variations in the Calculated Costs are too Great	Accepted NUB Application (with procedure code) Antibody-coated 2008-2011 Non-drug-eluting Bifurcation 2007-2010 Drug-eluting Bifurcation 2009-2011	Negotiable Supplementary Payment Radioactive 2005 Drug-eluting 2004-2008 Drug-eluting Bifurcation 2007-2008	Unique DRG
Without Procedure Code		Accepted NUB Application (without procedure code) Antibody-coated 2007 Non-drug-eluting Bifurcation 2006		

Figure 1. Integration of different stent technologies in the G-DRG system. Source: Henschke et al.: Extrabudgetary (NUB) payments a gateway for introducing new medical devices into the German inpatient reimbursement system?

do so. Consequently, only a small percentage of patients may have access to these products at such an early stage. This may, however, be justified as at this stage it is often unclear whether these products are indeed superior to conventional technologies. Unfortunately, the cases receiving NUB reimbursement are not systematically evaluated, so that this assessment opportunity is lost in Germany.

Additionally, it must be emphasised that individual hospitals and sickness funds negotiate NUB reimbursement on a case-by-case basis. Details about these agreements are rare and have not been made public. As a result, it is impossible to draw conclusions about the content of these agreements or the size of negotiated payments.

Procedure codes created for coronary stents between 2004 and 2011 cover a broad ambit of stent technologies. The G-DRG is a learning system that continually accounts for new technologies. However, the G-DRG classification does not distinguish between different stent technologies by means of unique DRGs, rather it distinguishes through supplementary payments made on top of existing DRG reimbursement. In the case of an absence of supplementary or NUB payments, hospitals still have the opportunity to subsidise cost-increasing technologies through other DRGs or hospital services. If technological innovation improves the reputation of hospitals (which is likely for innovative vs. "old" stent technologies), they possibly will react by offering such cost-increasing services.¹²

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