Negative Pressure Wound Therapy: Reimbursement situation 15 years after entering the European Market

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LETTER TO THE EDITOR

***Abstract*—Getting adequate reimbursement for new and innovative medical devices is crucial for a successful uptake of the product in the market. However in the last years payers and authorities pushed for more detailed evaluations of the actual benefits of new medical devices before granting reimbursement. These assessments are often based on established Health-Technology-Assessments methods developed for pharmaceuticals. But as medical devices and pharmaceuticals differ in many ways these processes often do not work as smoothly as hoped and necessary. The history and current reimbursement situation of Negative Pressure Wound Therapy (NPWT) is an example for this. Despite being on the market for over fifteen years in Europe and backed up by clinical and economic studies only Germany, Switzerland, Netherland, Sweden and Slovakia do have a dedicated reimbursement for NPWT in the inpatient sector. In the outpatient sector the reimbursement situation is even worse as only Switzerland and Austria have a fully functioning reimbursement. In Germany reimbursement decision are taken on a case-by-case base while in England only the dressings are reimbursed but not the equipment itself. In France, only usage in the home hospitalisation sector is reimbursed. This situation can be unsatisfying for patients, physicians, payers and manufacturers. In order to improve the uptake of new medical devices manufacturer need to focus earlier on creating solid clinical evidence while payers also have to adapt their health-technology-assessments and take the differences of medical devices compared to pharmaceuticals into account.**

***Keywords*—NPWT, reimbursement, Europe, medical device**

I. Introduction

IN the European Union, the market approval of a medical device in one member is sufficient to get access to all markets via the Conformité Europeénne (CE) process. A device with a CE-mark ought to be safe and function for the intended use as specified by the manufacturer.[1] However, market approval is just the first step in commercializing innovative medical devices. In most European health-care systems dedicated product reimbursement granted by publicly funded health-care systems or health funds is the key for widespread adoption of the device. But in contrast to market approval via the CE-mark reimbursement decisions are a national task and often differ from country to country. In countries like Spain and Italy reimbursement even varies from region to region as the provision of health care is under the responsibility of the different regions.

One common feature of the reimbursement systems in most countries is the use of Health-Technology-Assessments (HTA) for innovative, high-risk or costly medical devices. The aim of these assessments is to evaluate the therapeutic benefits e.g. improvement in co-morbidity, mortality and quality of life of a new device or treatment method compared to the current standard of care. In addition countries (e.g. United Kingdom (UK) and the Netherlands) also demand cost-effectiveness.[1]

These health-technology-assessments were developed and first used for pharmaceuticals but often act as a blueprint now for medical devices.[2] As devices are however different in functioning, the undertaken assessments are often ill fitted for devices and hence often turn out to be very lengthy, reach inconclusive results and fail to offer clear guidelines how to incorporate the devices into the reimbursement system. Success of a medical device depends on the functionality of the product as well as skill and experience of the user. Moreover, innovative products often differ from old ones and hence users need time to learn how to use it properly. However in clinical trials this extra time is in general not available. Hence it is unclear if results of an Randomized Controlled Trial (RCT) show the difference in the user-experience with the new device or really the difference between the different procedures or products used.[2] The execution of the RCTs, the cornerstone of all HTAs, is for devices further complicated due to the fact that blinding of procedures is often not possible and that devices are modified frequently after initial development and therefore by the time an RCT is finished the product might have changed profoundly already.[1]

One example of a fairly novel treatment method is Negative Pressure Wound Therapy (NPWT). NPWT is used to treat acute and chronic wounds and was established over the last 20 years in the USA and Europe. The cornerstone of the therapy is the distribution of negative pressure over the whole wound surface area. The setup consists of a dressing which is put into the wound cavity and connected to a vacuum pump via tubing followed by a sealing with an airtight, water-vapor-permeable transparent and germ-tight polyurethane adhesive film. The vacuum pump maintains a controlled negative pressure usually

Manuscript received 23.09.2015; revised 4.02.2016. This work received financial support form PAUL HARTMAN AG

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between -50 to -200 mm Hg. Removed wound exudate is either stored in an attached container or in the dressing itself.[3]

The main clinical benefits of NPWT are: reduction of wound area by contraction of wound margins, the granulation tissue formation by mechanically induced cell proliferation, wound cleansing due to removal of cell debris and elimination of wound exudates along with the cytotoxic compounds.[3] Described economic benefits of NPWT are cost savings due to: faster and better healing of wounds, faster wound bed preparation necessary for further surgical wound closure techniques and earlier discharge from the hospital.[4] NPWT is currently available in all European countries with the overall market estimated to be around 440 Million €.[5]

II. Objective

The aim of this research was to assess and discuss the current reimbursement situation of NPWT in various European countries almost 15 years after the first commercial NPWT-systems entered the European market. With this insight the question was asked what lessons the NPWT-example can teach us about the market access and reimbursement possibilities for novel medical devices in Europe.

III. Methodology

The results of this study were based on a survey of NPWT-experts conducted by PAUL HARTMANN AG (Heidenheim, Germany) in various countries. They were asked about the reimbursement situation of NPWT in their respective country either via telephone conference or face-to-face interviews. In total seventeen internal experts from eleven countries were questioned. In addition two external experts were asked about the NPWT-markets in the UK and The Netherlands. The survey was conducted between November 2014 and March 2015.

IV. Results

A. Current NPWT-reimbursement in the inpatient sector:

European hospitals are predominantly financed via Diagnose-Related-Groups (DRG)-payment systems.[6] In this payment-system a hospital receives a fixed amount of money for each patient depending on the diagnosis, comorbidities and the undertaken procedures for the patient. Hence payment for treatment services and treatment products is not separated as in the outpatient sector (with exceptions for e.g. very expensive drugs or treatments in some countries).

In order to understand the current reimbursement status of NPWT it is crucial to know the basics of hospital financing.

DRGs are a form of patient classification scheme which is characterized that patient discharge data (Diagnoses, concomitant diagnoses, procedures, demographic data . . .) are routinely collected to classify patients into groups (DRGs) using a fixed algorithm. The groups have to be clinically and economically homogenous.[6]

Hence DRGs provide the possibility to summarize a huge number of individual patients into a manageable number of groups (e.g in Germany about 18 million patients are grouped into just 1100 DRGs). This makes hospital activities comparable and therefore allows for a more fair hospital payment system.[6]

There are some basic elements all DRG-Systems need:[6]

- A fixed set of DRGs (between 500-2500)
- A set of diagnosis codes: usually versions of the international classification code for diagnosis ICD-10 (about 16000 codes)
- A set of procedure codes (up to 25000 codes)
- A software to calculate the DRG as a combination of usually main diagnosis, side diagnosis and procedures
- A relative DRG-hierarchy based on resource consumption, this can be in monetary terms or weights or scores

Additional elements of DRG-systems include:

- A fixed date for revision of the system
- Detailed cost calculation for each DRG
- An organized way to fund innovative products and procedures.

For innovative devices this funding mechanism provides some serious obstacles. Ideally all innovative devices with proven clinical benefits would get a dedicated procedure code or DRG in order to compensate the hospitals for the equipment costs.

However not all DRG-systems are updated regularly and it takes usually at least two years that innovative devices can trigger the grouping of patients into a better paid DRG (one year for data collection and one year for data analysis). Therefore the usually higher unit cost of innovative devices are not covered by the regular hospital payment system but have to be paid out from the general hospital budget. But as the share of hospital payment received via DRGs is quite high in most countries, the hospital management is often reluctant to dedicate extra money for new devices or treatment methods not explicitly covered in the DRG-system.

In the inpatient sector the results of the survey showed that only in a few countries dedicated NPWT-reimbursement is available via the DRG-systems (see Table 2).

In 2015 Germany had the most detailed NPWT-reimbursement scheme in Europe and it showed a clear evolution of reimbursement together with the therapy. Hence the introduction of NPWT in Germany is shown in more detail as a case-study how the reimbursement could happen. NPWT was not included at the start of the DRG-system in 2003 and overall it took five years from the launch of NPWT in Germany (around 2000) to be included via special NPWT-procedure-codes. The arguably more important special NPWT-DRGs were established in 2007 - just around the time when the first competitors arrived to challenge the monopoly of the developer of this method KCI (San Antonio, USA) (Fig. 1).[7]

Since 2005, a dedicated process to enhance the uptake of innovations in the German DRG-system was developed - the so called “Neue Untersuchungs-und Behandlungsmethoden” (NUB; New Diagnostic and Treatment Methods Regulation). Aims of this scheme are on one side to provide temporary funding until a medical innovation is incorporated into the system as well as giving the system enough time to generate enough data to decide if and how to integrate this innovation

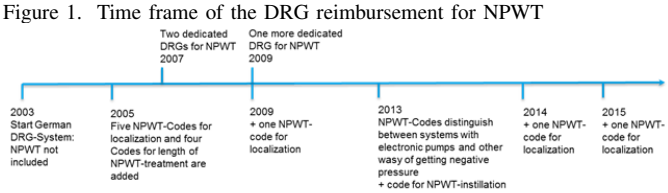
Table I
AN OVERVIEW OF THE DRG-SYSTEMS IN SEVERAL EUROPEAN COUNTRIES

Country	DRG-Name	No. Groups	Updates	Extra payments for innovations	Share of budget paid by DRGs
Austria	LKF: Leistungsorientierte Diagnosefallgruppen	979	Not regular	No	96%
England	HRGs: Healthcare resource groups	1389	Annually	Yes	60%
France	GHMs: Groupes homogénes des malades	2297	Annually	Yes	80%
Germany	G-DRG: German diagnoses related groups	1100	Annually	Yes	80%
Italy	There is a DRG-System but it does not apply to all hospitals. A lot depends on the region.				
Netherlands	DBC: Diagnose Behandeling Combinaties	30000	Not regular	No	84%
Poland	JGP: Jednorodne Grupy Pacjentów	518	Not regular	No	60%
Portugal	GDH: Grupos de Diagnósticos Homogénous	669	Not regular	No	80%
Slovakia	Currently no DRG-System, planned introduction in 2017 based on German-System				
Spain	Not really, some codification but no national system – Regions can have system, example Catalonia				
Sweden	NordDRG	983	Annually	Yes	Region specific
Switzerland	Swiss-DRGs	1100	Annually	No	Unknown

Table II
COUNTRIES WITH DEDICATED REIMBURSEMENT FOR NPWT

Country	NPWT reimbursement Inpatient Sector
Austria	
Czech-Republic	With restrictions
England	
France	
Germany	Yes
Hungary	
Italy	
Netherlands	Yes
Poland	With restrictions
Portugal	
Slovakia	Special NPWT-budget
Spain	
Sweden	Yes
Switzerland	Yes

Figure 1. Time frame of the DRG reimbursement for NPWT



into the system.[6] However in the case of NPWT this process was unavailible at this time. An overview about the current reimbursement situation of NPWT in the German-DRG-system is illustrated in Table 3.[8]

Switzerland introduced a DRG-system based on the German version. However it made some changes to the procedure codes and also increased the number of NPWT- DRGs (Table 4).[9]

Next to these two countries The Netherlands and Sweden do have special NPWT-codes for NPWT but however no dedicated NPWT-DRGs :

- The Netherlands[10]
  - 38952: Changing wound dressing serving vacuum therapy
  - 38953: Vacuum therapy in wound management, including initial application wound, clinical, per day
- Sweden[11]
  - DQ023: Vacuum treatment of wound.

Slovakia is using a different funding system as it has got no DRG-system yet in place. NPWT is on a national list for essential medical products with set prices. There is a fixed yearly budget for NPWT on a national level. The budget is then distributed among the hospitals using NPWT (negotiations between insurance companies and hospitals) and each hospital has got a fixed budget per month which is not transferable to another month. If for one month all the money is spend already the hospital can apply on a case by case basis for extra money or has to fund the NPWT-cost with their own budget. Poland and Czech-Republic offer some codification opportunities for NPWT however these are very limited and restricted. All other countries do not have a dedicated NPWT-reimbursement in the inpatient sector.

B. Current NPWT-reimbursement in the outpatient sector:

In almost all countries there is a separation between the payment of services and products in the outpatient sector, meaning no bundling of healthcare as in a DRG-system. Therefore if NPWT is not on the reimbursement list, no payment mechanism exist and hence outpatients do not have access to NPWT (Table 5).

Reimbursement in this sector usually depends on positive recommendations by health authorities which base their de-

Table III
CURRENT REIMBURSEMENT SITUATION OF NPWT IN THE GERMAN-DRG SYSTEM

DRGs for NPWT	Requirements: four defined surgical operations, at least 8 days of NPWT-treatment and one application / change for NPWT
G35Z	Complex vacuum therapy of illnesses and disturbances of digestives organs
J35Z	Complex vacuum therapy of illnesses and disturbances of dermis, hypodermis and mamma
I98Z	Complex vacuum therapy of illnesses and disturbances of muscular-skeleton-system and connective tissue
NPWT-OPS-Codes 2015	
Localization and kind of NPWT; note procedure needs to be done under anesthesia	
5-916.a0	Application or change of NPWT-system on dermis and hypodermis
5-916.a1	Application or change of NPWT-system, deep reaching, subfacial, on bones and joints of extremities
5-916.a2	Application or change of NPWT-system, deep reaching, on Thorax, Mediastinum and sternum (breast bone) including post cardiologic surgery
5-916.a3	Application or change of NPWT-system, open abdomen
5-916.a4	Application or change of NPWT-system, endorectal
5-916.a5	Application or change of NPWT-system, deep reaching subfacial on abdominal wall, or in areas next to fascia sutures respectively peritoneum
5-916.a6	Application or change of NPWT-system, endo-esophageal
5-916.ax	other, including retroperitoneum
Length of NPWT-treatment:	
8.190.20	NPWT for up to seven days
8.190.21	NPWT for 8-14 days
8.190.22	NPWT for 15-21 days
8.190.23	NPWT for more than 21 days

cision on the results of health technology assessments. Often this process is regulated with strict timelines. However as these evaluation methods are derived from processes and methods developed for pharmaceuticals they do not work as smoothly as needed.

One example for that is the case of Germany. The question of NPWT-reimbursement is not yet answered even as the application process was already started in 2002 (Fig. 2).[12, 13] The bodies instrumental for getting reimbursement in Germany are the "Gemeinsamer Bundesausschuß (GBA)" a decision body composed of payers, physicians and hospitals and the "Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWIG)" the organization responsible for conducting HTAs in Germany.

To bridge the time until a final decision about the reimbursement of NPWT is taken by the GBA the funding of NPWT in this sector is not ruled out but based on a case-by-case analysis.

The prescribing physician needs to fill out the request for funding detailing the clinical reasons why the patient has to be treated with NPWT. Often this process is organized by the provider of the NPWT-equipment and if the funding is granted by the health-fund then the provider (either a NPWT-manufacturer or an outpatient health care provider group) delivers the equipment to the patient. Furthermore the provider is also responsible for dressing changes and the smooth functioning of the system. There are varying reimbursement rates as each health fund negotiates with each manufacturer set prices per therapy day. Unfortunately the willingness to pay varies greatly from health fund to health fund hence a lot of patients are denied the recommended therapy.

In Austria the procedure and reimbursement situation is similar however there the health funds usually accept the request for NPWT treatment as demanded by the physician.

A comparable system also exist in Switzerland but in contrast to Austria and Germany all application for NPWT-treatment in the outpatient sector are automatically granted as long as they are prescribed by a qualified physician. Furthermore the price per treatment day is fixed for all device manufacturers and not negotiated separately as in Austria and Germany.

In England NPWT-dressings are listed in the drug tariff, however equipment rental cost have to be paid from the regional health care budget.

In Slovakia and The Netherlands some smaller single-use NPWT-devices are part of the outpatient reimbursement list. In Sweden there is no separation into in-and outpatient sector for complicated wounds as these patients are all treated at the hospitals regardless if they stay overnight or not. Hence NPWT is there paid out of the general health care budget for the region.

In the outpatient sector in France no reimbursement is available. However in the French health system a special sector exist called l'Hospitalisation A Domicile (HAD) which delivers health-care at home and is regarded as an extension of the hospital.[14] This service is delivered by private or public companies who get fixed funding per patient from the healthcare system which includes the use of NPWT if needed. The necessity of NPWT is determined by the hospital physician. The patient has to come back to the hospital once

Table IV
THE CURRENT NPWTJ REIMBURSEMENT SITUATION IN SWITZERLAND

NPWT-DRGs	Requirements: four defined surgical operations, at least 8 days of NPWT-treatment and one application/change for NPWT
G35Z	Complex vacuum therapy of illnesses and disturbances of digestives organs
I98Z	Complex vacuum therapy of illnesses and disturbances of dermis, hypodermis and mamma
J02A	Skin transplantation, flap surgery, extensive lymphadenectomies, mesh transplantation microvascular anastomosis with complex vacuum therapy and multiple comorbidities
J02B	Skin transplantation, flap surgery, extensive lymphadenectomies, mesh transplantation microvascular anastomosis with complex vacuum therapy without multiple comorbidities
T36Z	Intensive care complex treatment >392/522 effort points or complex vacuum treatment for infectious and parasitic diseases
W01B	Poly trauma including ventilation or craniotomy, or complex vacuum treatment or microvascular intervention, without early rehabilitation, with ventilation >120 h
NPWT-CHOP-Codes 2015	
Localization and kind of NPWT; note procedure needs to be done with anesthesia	
86.88.50	Application or change of NPWT-system, deep reaching, on bones and joints of extremities
86.88.51	Application or change of NPWT-system, deep reaching, on Thorax, Mediastinum and sternum (breast bone)
86.88.52	Application or change of NPWT-system, open abdomen
86.88.53	Application or change of NPWT-system, endorectal
86.88.59	Application or change of NPWT-system, on skin and hypoderm or any other localization
Length of NPWT Treatment	
93.57.11	NPWT for up to seven days
93.57.12	NPWT for more than seven days

a week but dressing changes can be done at home by a nurse trained on NPWT. In the other countries no reimbursement in the outpatient sector was available at the time of the survey.

V. DISCUSSION

Looking at the amount of time which passed since the introduction of NPWT in the European market, the huge number of scientific publication about this topic (until the end of 2012 over 1500 publication related to NPWT could be found on Medline®, now there are possibly over 2000) and the sheer number of patients treated with this therapy (e.g. for Germany in 2012 over 100.000 patients received NPWT in the hospital[15]) the difference in the reimbursement of this technology across various European countries is perplexing.

One explanation for that is that while market access and reimbursement pathways for pharmaceuticals in Europe follow established rules[16–18] the picture looks different for medical devices. Even as HTA bodies like the National Institute of health and care excellence in England (NICE) and IQWIG have published detailed guidelines[19, 20] the procedures do not work smoothly as seen with the example of NPWT in Germany (Fig. 2). Furthermore especially in the inpatient sector there aren't often clear pathways in the DRG-systems for innovations and even if these exist they are often cumbersome and attached to administrative obstacles.[6]

Table V
THE REIMBURSEMENT SITUATION OF NPWT IN THE OUTPATIENT SECTOR IN 2015

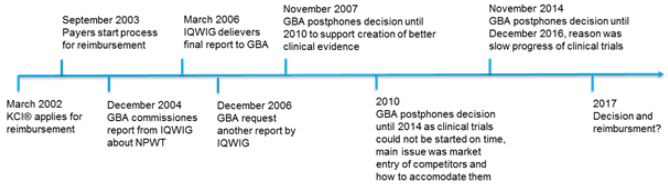
Country	NPWT reimbursed in the outpatient sector
Austria	With restrictions
Czech-Republic	No
England	Dressings reimbursed
France	With restrictions
Germany	With restrictions
Hungary	No
Italy	No
Netherlands	Yes
Poland	No
Portugal	No
Slovakia	Yes
Spain	No
Sweden	Yes
Switzerland	Yes

Despite the numerous scientific studies, which include also a number of RCTs with positive results, all systematic review published by HTA-bodies or other independent organizations questioned the quality of the evidence supporting the benefit claims of NPWT. Some of the criticism involved the use of questionable endpoints, the small number of trial participants or the use of wrong comparators, e.g. traditional gauze products instead of modern wound care products.[21] One example for this opinion is the assessment by the German IQWIG which stated in its last report in 2007 that overall the studies hinted that NPWT has a positive effects on wound healing but that the quality of the clinical trials still was poor.[22] A similar vague verdict about the benefits of NPWT was published by the French HTA-body HAS in 2010. While not convinced by the clinical evidence available at that time the experts still concluded that NPWT is of value in special circumstances.[23]

There exist a variety of reasons which complicate the generation of strong clinical results via the gold standard randomised controlled trials for NPWT:

- Success of NPWT therapy depends not only on product but also experience of user
- HTA-bodies put strong emphasis on endpoint wound healing:
  - Wounds treated with NPWT are often hard to heal ulcers therefore a very long study duration is required which is often not possible due to high cost and administrative burdens.
  - NPWT is only suitable for part of the wound healing process and the other used products also influence

Figure 2. NPWT-reimbursement application process



the outcome.

- Wounds derive from a variety of different etiologies e.g. venous leg ulcers, pressure ulcers, fractures, ... which all command different treatment regime:
- Difficult to recruit a large homogenous patient group and get significant results
- Free-rider problematic: As devices on the market are interchangeable all companies benefit from positive evidence but only one company has to pay for the cost for the studies. Because of that no company is willing and able to invest huge sums into large clinical trials.

These issues can exemplarily be seen in the German example for NPWT (Fig. 2). The overall the decision process already lasts more than 13 years and is expected not to be finished for another two years. Even, as it is in this case, payers and manufacturers are forced to work together by the authorities, the creation of adequate clinical evidence is still difficult, lengthier than expected and clear results are still far from certain. This example also showcases the free rider problematic as one reason for the delay of the clinical trials were the onset of competition in the German NPWT-market. The question who foots the bill for expensive clinical trials when everybody shares the rewards in terms of sales increases later? In the end the two main manufacturers at that time shared the cost of the equipment while the health funds paid for the treatment cost.[12]

In the inpatient sector the disputed clinical value of NPWT has led to varying reimbursement situations as described in Table 2. However due to the bundling of services and products into DRGs there is still a high acceptance of NPWT in this sector even in countries without special reimbursement. In all surveyed countries NPWT is an established therapy and used in the hospitals, especially in teaching hospitals as these are often willing to pay more for innovations and also have the means for it. More and more hospitals are willing to accept that NPWT is more cost effective when taking the broader view of complete treatment cost and not just unit cost of the equipment.

But it needs to be noted that due to budget constrains it is becoming more and more common that decisions about usage of expensive devices are made by the hospital's management from a business view and not by physicians from a clinical view as it was in the past.

In the outpatient sector there is usually a separation between the payment of services and products, meaning no bundling of health care as in a DRG-system. Therefore if NPWT is not on the reimbursement list there is no payment mechanism existing and outpatients do not have access to NPWT. As seen in Table 3 this is the case in most of the European countries. And even if there is some reimbursement it is often restricted to individual decisions which can be arbitrary as no clear guidelines exist. One particular issue here are patients who start NPWT in the hospital and could be discharged from hospital earlier would it not be for the fact that the treatment is not financed in the outpatient sector. Because of that physicians are faced with the decision either to keep a patient longer at hospital than necessary or discharge the patient earlier and deny him the treatment method deemed best. To have a reliable financed treatment pathway for these patients could potentially lead to huge cost savings for the health-care system as inpatient care is in general more expensive than treatment in the outpatient sector.[24] Another obstacle for the reimbursement in this area is the fact that the usage and dressing changes for NPWT requires experience and special skills. Therefore in contrast to other wound care products the patient or a relative cannot do the dressing change on their own. Hence the care-provider has to make sure that there are enough educated care-workers available who are able to handle NPWT-patients in the outpatient sector.

VI. Conclusion

Despite being on the market for 15 years there are still huge differences in the reimbursement situation of NPWT in Europe. Countries with established reimbursement are Germany, UK, Switzerland, Netherlands and Slovakia. In France reimbursement in the home-hospital sector is available. Lessons for other innovative medical devices from this example are that in the inpatient sector in Europe market access and significant revenues are possible without actually having a dedicated reimbursement already in place. This can be accomplished by either using special funding mechanisms available in some DRG-systems or more importantly convincing physicians and hospital management about the clinical and especially economic advantages of the new method. However to really establish a strong market with high turnover incorporation of the treatment method into the local DRG-system is crucial.

In the outpatient sector market access depends on getting dedicated reimbursement and this is difficult to obtain as seen with NPWT. Reimbursement decision processes are often based on established pharmaceutical pathways meaning strong clinical evidence based on RCTs. However the creation of solid clinical evidence for medical devices is often more tricky and not that straightforward as for pharmaceuticals. Furthermore the high cost associated with RCTs can often not be recouped due to weak patent protection and early onset of competition. Hence clinical evidence is often inconclusive which leads to lengthy reimbursement processes e.g. as seen with NPWT in Germany.

For the future however solid clinical evidence for medical devices will become even more important and medical device companies have to be aware that just adding new features to their devices and demanding a higher price will no longer be possible. Any innovation which commands a premium price will have to make a proven positive difference to patients or budgets.

VII. Acknowledgments

Without the knowledge and support of the following colleagues and experts this study would not have been possible. Hence I am very grateful to: Anna Lindeborg, Claus Essling, Eddy Verharen, Elzbieta Lyszkowska, Ewa Lewandowska, Giorgio Giusti, Giustino Affronti, Jana Jackova, Kateřina Červinková, Lars Holst, Laura Fernandez, Luca Del Pelo, Martina Laschet, Peter Schuck, Sandra Laurent-Germain, Sophie Lange

External advice was given by Consultants from Real Healthcare solutions® (UK) and Chris Borsten (ExtraCura®, Netherland).

References

[1] C. Sorenson, M. Drummond, and L. R. Burns, "Evolving reimbursement and pricing policies for devices in europe and the united states should encourage greater value," *Health Affairs*, vol. 32, no. 4, pp. 788–796, apr 2013. [Online]. Available: http://dx.doi.org/10.1377/hlthaff.2012.1210

[2] M. Drummond, A. Griffin, and R. Tarricone, "Economic evaluation for devices and drugs—same or different?" *Value in Health*, vol. 12, no. 4, pp. 402–404, jun 2009. [Online]. Available: http://dx.doi.org/10.1111/j.1524-4733.2008.00476_1.x

[3] C. Willy, *The Theory and Practice of Vacuum Therapy*. Ulm: Lindquist book-publishing, 2006.

[4] D. Nord, "Kosteneffektivität in der wundbehandlung," *Zentralblatt für Chirurgie*, vol. 131, no. S 1, pp. 185–188, apr 2006. [Online]. Available: http://dx.doi.org/10.1055/s-2006-921433

[5] M. Monitor, "European negative pressure wound therapy devices (npwt) market," 2015. [Online]. Available: http://www.micromarketmonitor.com/market/europe-negative-pressure-wound-therapy-devices-npwt-3843966498.html.

[6] A. Busse, Q. W., and W. M., *Diagnosis-Related Groups in Europe. European Observatory on Health Systems and Policies Series*, M. J. Figueras, E. Mossilos, R. B. Saltmann, and B. R., Eds. McGraw-Hill Education: Open University Press, 2011.

[7] Institut für das Entgeltsystem im Krankenhaus . [Online]. Available: http://www.g-drg.de/cms/

[8] Deutsche Institut für Medizinische Dokumentation und Information, "Operationen- und prozedurenschlüssel version 2015," 2015. [Online]. Available: http://www.dimdi.de/static/de/klassi/ops/kodesuche/onlinefassungen/opshtml2015/index.htm

[9] Office fédéral de la statistique (OFS), "Schweizerische Operationsklassifikation (CHOP) Systematisches Verzeichnis – Version 2015," 2015. [Online]. Available: http://www.bfs.admin.ch/bfs/portal/de/index/news/publikationen.html?publicationID=5660

[10] Werken met dbc's ziekenhuiszorg, "Praktische uitleg en documentatie bij de dbc-systematiek," 2015. [Online]. Available: http://werkenmetdbcs.nza.nl/zz-releases/algemeen-4/nu-geldende-documenten/menu-id-1954

[11] NordDRG ICD+ and NCSP+ platforms, "Basic classification," no. 2, 2014. [Online]. Available: http://www.nordcase.org/eng/materials/basic-classification/

[12] Gemeinsamer Bundesausschuss Abteilung Methodenbewertung und veranlasste Leistungen , "Vakuumversiegelungstherapie," *Zusammenfassende Dokumentation des Unterausschusses „Ärztliche Behandlung" des Gemeinsamen Bundesausschusses*, 2008. [Online]. Available: https://www.g-ba.de/downloads/40-268-538/2008-02-15-Abschluss-VAC.pdf

[13] Gemeinsamer Bundesausschuss, "Tragende gründe zum beschluss des gemeinsamen bundesausschusses über eine Änderung der richtlinie methoden vertragsärztliche versorgung: Verlängerung der aussetzung des bewertungsverfahrens zur vakuumversiegelungstherapie von wunden," 2014. [Online]. Available: https://www.g-ba.de/downloads/40-268-3009/2014-11-20_MVV-RL_Verlaengerung-Aussetzung-VAC_TrG.pdf

[14] O. TERRADE, T. TSUTSUI, and A. COTTENCIN, "Hospital care at home in france: an alternative to conventional hospitalization with the same obligations towards quality and administration," *Journal of the National Institute of Public Health*, vol. 61, p. 148.

[15] G. D. BUNDES, *Das Informationssystem der Gesundheitsberichterstattung des Bundes*. [Online]. Available: http://www.gbe-bund.de/gbe10/pkg_isgbe5.prc_isgbe?p_uid=gast&p_aid=0&p_sprache=D

[16] S. Sieler, T. Rudolph, C. Brinkmann-Sass, and R. Sear, "Amnog revisited," *Pharma Times*, 2015. [Online]. Available: http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/amnog-revisited

[17] National Institute for Health and Care Excellence, "Nice statistics," 2016. [Online]. Available: https://www.nice.org.uk/news/nice-statistics

[18] Haute Autorité de santé , "Our studies," 2005. [Online]. Available: http://www.has-sante.fr/portail/jcms/c_946986/en/english-toutes-nos-publications-ligne-principale?portal=r_1457306

[19] National Institute for Health and Care Excellence, "Nice medical technologies guidance," 2011. [Online]. Available: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance.

[20] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen., "Allgemeine methoden," 2015. [Online]. Available: https://www.iqwig.de/de/methoden/methodenpapier.3020.html

[21] aetna, "Negative pressure wound therapy," no. 0334, 2015. [Online]. Available: http://www.aetna.com/cpb/medical/data/300_399/0334.html

[22] IQWiG, "Vakuumversiegelungstherapie von wunden."

[23] M. Vaneau, "Evaluation of negative-pressure wound therapy," *Haute Autorité de Santé/Device Evaluation Department*, vol. 2, 2010.

[24] C. Dowsett, L. Davis, V. Henderson, and R. Searle, "The economic benefits of negative pressure wound therapy in community-based wound care in the NHS," *International Wound Journal*, vol. 9, no. 5, pp. 544–552, feb 2012. [Online]. Available: http://dx.doi.org/10.1111/j.1742-481X.2011.00913.x