Innovation for Safe and Effective Medical Devices:

Contributions from Post Market Surveillance

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Innovation for Safe and Effective Medical Devices:
Contributions from Post Market Surveillance

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ABSTRACT

Background

Recent years have seen great interest in finding new ways to develop innovative, safe and effective medical devices. While there has been considerable research on the lead user and open innovation approach, relatively little attention has been given to post market surveillance as a valuable source of safety-related information on medical devices. We wanted to find out (a) what instruments medical device manufactures use to promote an internal transfer of post market surveillance knowledge and (b) to what extent this can lead to impulses for Research and Development (R&D) meant to improve or develop new medical devices. Our results, collected in a German-wide online survey of 118 post market surveillance experts, show that especially technical and human resource-related instruments are of high importance for an intra-organizational transfer of post market knowledge. We then found out that the transfer of this post market-related device knowledge can have a positive impact on the improvement or development of (especially incremental) medical device innovations, thus contributing to the company's success and strengthening device-related patient safety at the same time.

Methods

An online questionnaire was sent to 118 postmarket surveillance experts throughout Germany to find out (1) what instruments medical device manufactures use to promote an internal transfer of postmarket surveillance knowledge and (2) to what extent this can lead to impulses for research and development meant to improve or develop new medical devices.

Results

Our results showed that technical and human resource-related instruments are of particularly high importance for the intraorganizational transfer of postmarket knowledge.

Conclusion

The transfer of this postmarket-related device knowledge can have a positive impact on the improvement or development of (especially incremental) medical device innovations, thus contributing to a company’s success and strengthening device-related patient safety at the same time.

Keywords

Innovation management; Knowledge transfer; Post marketing; Product surveillance; Quality and risk management; Regulation

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INTRODUCTION

Background

Given an intense competitive environment in the medical device sector, manufacturers will only be successful in the long term if they can continuously generate impulses for the development or improvement of new medical devices [1, 2]. Therefore, medical device companies are constantly looking for more knowledge sources to find innovative ideas and new solutions that generate benefits for users or patients in terms of better and safer diagnosis or treatment.

A look at the international literature will show that the consideration of external device-related knowledge plays an important role in the innovation process of the manufacturers. According to a study by SHAW, 26 of 34 (76%) device innovations from eleven British medical device companies were developed through interaction between the company and the users of the company's devices [3]. BIEMANS analyzed 17 cases of innovation from 13 cooperating companies of the Dutch medical equipment industry, of which nine (53%) were characterized as a device development process initiated by a user or third party [4]. LÜTHJE showed in an empirical study based on interviews with 261 surgeons from German university hospitals that users of surgical equipment can contribute substantially to the device innovation process as innovators or co-developers [5]. LETTL examining five case studies of radical innovations in four medical device companies found that in four cases advanced users dominated the R&D process [6].

The studies mentioned above suggest that companies can generate impulses for the development and optimization of medical devices in the device environment both within and outside the company. As a matter of fact users such as physicians or nurses often know best how medical devices are used in clinical care, where problems and difficulties during application may arise, and what the users' needs and wishes for device development and innovation actually are. Therefore, companies should integrate external user information and knowledge as a valuable source for improving devices for clinical care and for developing new ones [7-9].

Purpose and scope of our study

With respect to generating innovative product information from external knowledge sources manufacturers have recently pursued different strategies that go beyond internal R&D. Among the approaches on innovation management and product development of medical devices discussed in literature, the most prominent are the lead user [10-13] and open innovation approaches [14, 15]. In contrast, our study focuses on methods used by manufacturers to systematically collect and analyze safety-related data of approved equipment (post market surveillance), a valuable source for innovation impulses rather neglected in literature so far. The organizational conditions for generating and transferring post market knowledge are not bad. This is because the companies are obliged by law to implement a system, as part of their quality management, through which they can

systematically monitor all their medical devices on the market [16, 17]. As a matter of fact it is not possible for the manufacturers, despite all their efforts in the development, design and approval process (pre-market phase), to cover all conceivable risks, complications or outcomes of approved medical devices in every kind of clinical application [18-20]. By identifying device-related safety knowledge, adverse events, or hazards occurring in clinical environment can be investigated and patients protected from complications and health risks. For this purpose companies can consider several knowledge sources, e.g. device-related incident reports [21-23] or alerts and recalls issued by competent authorities like FDA, BfArM, MHRA or Swissmedic [24-26].

The innovation potential resulting from post market knowledge for medical device companies is obvious: it creates device-related risk information and thus specific technical and user knowledge and impulses for R&D as to how new medical devices or already existing medical devices and pro-cesses can be designed more efficiently and effectively, resulting in ergonomic, safer and better device use and risk reduction. Given the importance of both knowledge transfer and innovation management in medical technology, we were especially interested in finding out

(a) what instruments manufacturers use for the systematic transfer of safety-related post market knowledge between the departments of post market surveillance and R&D and
(b) whether and to what extent this can lead to impulses for the development of new devices.

MATERIAL AND METHODS

To answer these questions, we performed a study of manufacturers engaged in the German medical device market.

The sample

We searched the membership lists of the following trade associations for medical technology in Germany: (i) German Medical Technology Association (BVMed), (ii) German Hightech Industry Association (SPECTARIS – Fachverband Medizintechnik), (iii) Association of the Diagnostics Industry (VDGH) (total 466, Date: March 2014). We only included manufactures that had a location in Germany and were subject to post market surveillance. Duplicate entries were removed. The focus on association members was motivated by the idea that thereby companies of different sizes (SME, large enterprise) from all over the country were included in the sample. Finally, we saw to the fact that manufacturers with medical devices of all risk classes as well as Active implantable medical de-vices (AIMD) and In vitro diagnostics (IVD) were considered; risk classes as defined by the European Commission (see table 1, [27]). In total, 324 medical device companies were included in the study sample.

Questionnaire and measurement

Internal knowledge transfer

As regards the first objective, medical device companies were asked to assess how often they used each of a total of 21 instruments for the internal transfer of post market knowledge. The instruments, drawn from existing literature on knowledge management, were compiled and categorized into three dimensions [28]:

- *Technology;*
  This relates to the support of information and communication technologies. Recent years have seen the development of many software applications, through which a large amount of (post market) knowledge can be stored systematically and distributed throughout the company, e.g. electronic complaint- or document management systems.
- *Organization;*
  Internal handling of post market knowledge needs structures and processes which determine and control the transfer of dissemination of knowledge on an organizational level. This includes, for example, a knowledge officer or communication channels.
- *Human Resources.*
  These are instruments meant to motivate employees to analyze post market knowledge in terms of innovation potentials and to share their knowledge within the company. Examples include a climate of openness and trust in each other, or monetary incentives for knowledge sharing.

Innovation potential

With regard to the second aim, the companies were asked to assess to what extent the internal transfer of post market surveillance knowledge affected their innovativeness, particularly the degree of innovation (radical or incremental [29]) and the type of innovation (product, process or clinical care process). Table 2 illustrates the typology of innovations and gives examples from the field of the medical device industry.

The data collection was based on a six-point Likert scale with the two anchors 0 (“unavailable” or “never”) and +5 (“very often/always”). To increase the response rate all questions could be skipped by answering "not specified".

To create subgroup-specific analyses we were finally interested in company-specific characteristics. We were particularly interested in the size of the company (SME or large enterprise), company classification as defined by the European Commission for SMEs [34], and the risk class(es) of produced devices (table 1, multiple answers possible). With regard to grouping, the highest self-reported risk class was decisive. Moreover, manufactures producing AIMD and class III devices as well as manufacturers of all IVD classes (IVD Annex II List A, IVD Annex II List B, IVD Devices for self-testing, IVD General) were evaluated in one sub-group.

Data collection and analysis

Data were collected in the second quarter of 2014, based on a nationwide online survey. We used a two-step approach: first, telephone contact with a post market surveillance expert in each of the sampled companies and

second, personalized invitation to participate in the online survey via Email. A week before the end of the survey, a reminder was mailed to all participants to improve the response rate.

We analyzed data using descriptive analysis by IBM SPSS Statistic Software® (Version 22.0) for Microsoft Windows® 7. The significance of the mean differences between selected groups of companies was verified using the non-parametric two-sided Kruskal-Wallis test (p=0.05).

RESULTS

The survey was completed by 118 medical device manufacturers, for a total of a 36% return rate. Of these, 48 (41%) were SMEs, 45 (38%) large enterprises. 25 (21%) could not be classified due to insufficient information. Manufacturers of all risk classes participated in the survey. The sequence was as follows: Class IIa (68%), Class I (66%), Class IIb (55%), Class III (37%), IVD (23%) and AIMD (2%). Regarding the highest self-reported medical device risk class, 44 manufactures (37%) produced AIMD/Class III devices, 27 (23%) Class IIb devices, 22 (18%) IVD, 16 (13%) Class IIa devices and 9 (8%) Class I devices.

Internal transfer of post market knowledge

Mean values and standard deviations of the self-reported frequency of use of the instruments for the internal transfer of post market knowledge are shown in table 3 according to the three dimensions (technology, organization, human resources).

The instruments most frequently used for knowledge transfer were Groupware system/Email, followed by Complaint management system, cooperative style of leadership/teamwork, climate of openness and trust, leeway for employees, and understanding of knowledge sharing by top management. Results showed lowest utilization rates for non-monetary incentives for knowledge sharing, knowledge balance sheet, knowledge officer and monetary incentives for knowledge sharing.

Sub-group analysis: Means broken down by company size and highest medical device risk class showed higher significant group differences for the use of the following knowledge management instruments:

- Workflow management system: frequently used by large enterprises (difference from the overall mean of the instrument: +0.9; asymptotic significance: $p < 0.01$) and manufacturers of AIMD/Class III devices (+0.6), while used below average by SMEs (-0.9) and companies producing Class I devices (-0.7) and IVD (-1.2).
- Complaint management system: particularly used by manufacturers of AIMD/Class III devices (+0.6; < 0.001) and IVD (+0.5), less often by companies of Class IIb (-1.0) and Class IIa (-0.6) devices.
- Document/content management system: relatively highly rated by large enterprises (+0.7; < 0.001), less by SMEs (-0.9).

- Digital information/discussion portal: relatively often used by large enterprises (+0.5; < 0.05) and companies producing AIMD/Class III devices (+0.5), hardly used by SMEs (-0.7) and manufacturers of Class IIa devices (-0.6) or IVD (-1.0).
- Formalized knowledge storage: particularly used by companies producing AIMD/Class III devices (+0.8; $p < 0.05$), while used below average by manufacturers of Class IIb (-0.5) and Class I (-0.7) devices.

Innovation potential

Table 4 shows the ranking of innovation types, through which the internal transfer of post market knowledge can most likely lead to innovation impulses. Incremental improvement of a medical de-vice comes first, followed by incremental improvement of a manufacturing process, radical improvement of a medical device, and radical improvement of a manufacturing process. Laggards are incremental and radical improvement of a medical device-related clinical care process.

Sub-group analysis: Means broken down by manufacturer groups showed larger significant differences for the two innovation types with the lowest overall ranks:

- Incremental improvement of clinical care process: this occurs relatively often among large enterprises (+0.7; $p < 0.001$) and manufacturers of AIMD/Class III devices (+0.9), while hardly occurring in SMEs (-0.7) and companies of Class II devices (-1.0).
- Radical improvement of clinical care process: this occurs relatively frequently in companies producing AIMD/Class III devices (+0.5; $p < 0.001$), while SMEs (-0.5) and manufacturers of Class IIa devices (-0.9) benefit comparatively less.

DISCUSSION

This is the first empirical study on the internal transfer of medical device-related post market information between the departments for post market surveillance and R&D, and the potential it has for increasing innovation. This last section of the paper discusses the results as well as research-related and managerial implications of the study. Finally, central methodological limitations of our research will be noted.

Internal transfer of post market knowledge

The first research aim was to gain knowledge about the manufacturers' structures for internal transfer and management of post market knowledge. The results show that the manufacturers use many different instruments for the internal transfer of medical device- and process-related information between the departments for post market surveillance and R&D; however, this leaves still room for improvement, which is demonstrated by the fact that the overall means for all instrument categories were estimated between "rare" and "occasionally" on the Likert scale: technology (2.9), human resources (2.7) and organization (2.1). Regarding Groupware system/Email as the most commonly used instrument, one may assume that a lot of companies introduced this instrument primarily for communication, calendar function, etc., not specifically for the transfer of post market data. The most common systems are IBM Lotus Notes® and Microsoft Outlook®.

Moreover, the results indicate that technical instruments, such as complaint or content management system, and human instruments, such as creating a climate of openness and trust or a cooperative style of leadership/teamwork are on average used more intensively than organizational instruments. Furthermore, it was found that almost all technical instruments were used significantly more often by large manufacturers or companies producing AIMD/Class III devices. This is confirmed by the relatively high variances to these instruments (table 3). As a matter of fact, both can be considered as an indicator showing that for many medical device companies information and communication technologies as well as the use of Internet-based services are becoming increasingly important for a systematic knowledge transfer. For example, the complaint management system documenting feedback electronically from users on a regular basis, is rated one of the most important instruments to support the internal transfer of medical device-related post market knowledge. Apart from that, the results for human resource-related instruments show that staff-related aspects play an important role for a functioning internal knowledge transfer, for example, when encountering resistance from employees or when encouraging them to share and use medical device- and process- related post market knowledge across departmental boundaries.

Innovation potential

The second research aim focused on the potential of an internal transfer of medical device-related post market knowledge aiming at the increase of the manufacturers' innovation capacity. Here, we distinguished (i) type and (ii) degree of innovation (table 2).

Type of innovation

The internal transfer of post market knowledge can most likely lead to impulses for the (further) development of medical device innovations (table 4). It seems indeed easier to (further) develop a medical device on the basis of safety-related medical device knowledge than to improve a medical device-specific manufacturing process which necessarily touches several different organizational areas and structures. An example of the former is the extension of a medical device-specific briefing document on the basis of serious critical incident reports; an example of the latter would be to adapt an IVD manufacturing process as a result of frequently reported quality defects by laboratory physicians.

Particularly complex is the development of medical device-related clinical care processes, whereby procedures and processes have to be standardized, medical staff has to be trained, etc. However, sub-analysis showed a mixed picture here: 44% of the participating manufacturers producing AIMD/Class III devices estimated that the internal transfer of post market data "often" or "very often/always" promotes the incremental improvement of a medical device-related clinical care process. Many Class III devices are (non-) active implants, e.g. for heart rhythm disorders, vascular interventions or arthroplasty. This may indicate that device-related post market knowledge most likely influences the (further) development of clinical care processes (adapting surgical techniques, sensitizing users of device-related complications, etc.) in the medical fields of surgery, cardiology or orthopedics/trauma surgery. Assessment differences are also reflected in the relatively high mode and median of three to this type of innovation. It has to be mentioned, however, that approximately only two-thirds of the participants gave an answer to this special type of innovation.

Degree of Innovation

The results indicate that the transfer of post market knowledge leads more often to impulses for the (further) development of incremental than radical innovations (table 4). This, too, seems logical, because it is usually easier to slightly improve an already existing medical device (e.g. by updating a software system, changing an equipment part, etc.) than to fully develop a new medical device with new features/functions for a new market (table 2). The intuitive consideration that incremental innovations occur more often than radical innovations was thus confirmed by our research questions.

Research and managerial implication

In this section we discuss research-related and managerial aspects of the study.

Research implications

According to the study the transfer of post market knowledge can lead to impulses for the development of (especially incremental) medical device innovations. This promotes an understanding of post market surveillance as a complementary approach of Open Innovation, a paradigm (as defined by Chesbrough) that assumes that companies should use both internal and external knowledge sources and information for their R&D processes and innovation [15]. Consequently, post market knowledge becomes an important input factor for the manufacturers' innovation process and a success factor for internal R&D. Regarding the transfer and use of post market knowledge for R&D, the studies mentioned above [3-6], according to which external (user) knowledge can play a role in the medical device innovation process, were thus empirically confirmed.

Considering future studies it could be interesting to look at manufacturers in detail, since the implementation and use of knowledge transfer measures always depends on company-specific conditions (size, resources, etc.). (Multiple-) case studies could be carried out in this context. LETTL [6] shows that this method is suitable for innovation-related research in the medical device industry. Moreover, it could be interesting to explore the intensity of use of instruments for the internal transfer of medical device-related post market knowledge with regard to other characteristics than company size or risk class, e.g. the company's device portfolio or organizational structure. It could also be interesting to get information from other departments involved in the medical device innovation process, such as R&D or marketing/sales, or to look at the first steps of the medical device innovation process, i.e. from the start of development through product testing to market approval, which are also decisive for the long-term implementation of innovative medical devices and services on the market.

Finally, it would be interesting to examine whether other industries can benefit from the findings of our work, primarily pharmaceutical companies, equally required by law to implement a post market surveillance system due to the product-related risk potential for patients [35, 36], and equally characterized by a high level of innovation and competition (especially the research-based pharmaceutical industry). When comparing the two sectors, it is important, however, to take into account some fundamental organizational differences with regard to the management of post market knowledge. First, it can be assumed that drug manufacturers have more established structures for the transfer of safety-related product knowledge, because they have been obliged by law to implement post market drug safety surveillance instruments for a longer time as part of pharmacovigilance (in Germany according to the Medicinal Products Act, AMG).

Moreover, the pharmaceutical industry is (especially in contrast to the German medical device sector, which consists of mainly small and medium-sized enterprises) characterized by large manufacturers with usually more financial resources, which has probably a positive effect on the average use of instruments for the transfer of safety-related post market knowledge. In addition, manufacturers in both sectors can use different knowledge sources for post market surveillance.

For instance, device-related risk data in clinical trials and HTA reports is on average much better for medicinal products than for medical devices. For medical devices, however, exists a relatively large amount of data on device-related critical incidents and risks, published in Germany especially on the website of the Federal Institute for Drugs and Medical Devices as field corrective action, recommendation, etc. (http://www.bfarm.de/EN/MedicalDevices/riskinfo/_node.html) as well as in scientific journals [24, 26, 37, 38].

There are also differences in terms of R&D and innovation management. For example, the development cycles of drugs are usually significantly longer than those of medical devices. In addition, the innovation of clinical care processes is of little relevance for drug manufacturers, because the outcome of drugs is primarily been influenced by the chemical's effect on the body and not the user [39]. Our findings could also be of interest for companies producing devices in the fields of biomedicine, biochemistry or human biology, i.e. life sciences, which are in part subject to post market regulations, too. An example would be manufacturers that produce medical devices with a complementary drug ingredient such as cardiovascular or drug-eluting stents [30].

Managerial implications

According to our study, post market knowledge can be a valuable source for generating ideas and impulses for innovative, safe and effective medical devices and processes. The efficient and effective use of post market data may thus become a (strategic) successful competitive factor of the manufacturers. Consequently, it should be a key task for the company's strategic management to create organizational structures so that post market knowledge can systematically be made available to R&D. Since, due to legal requirements, post market knowledge has anyway to be generated by the manufacturers this could be an opportunity to continuously generate new ideas for medical device development – also for companies with limited R&D resources, as it is relatively inexpensive. The results also show that the manufacturers can take action to improve the internal knowledge transfer in all three dimensions. Further activities to promote internal knowledge transfer include the implementation of a post market-/knowledge management strategy or the provision of sufficient resources for knowledge processing.

We assume that management of medical device and process-related post market knowledge will play an even greater role in the medical device sector in the future due to an ever increasing use of medical devices as well as information and communication technologies and Internet-based services in healthcare. Companies will be challenged to manage a growing amount of medical device-related post market knowledge ("Big Data"), e.g. the variety of different knowledge sources such as medical device-related databases, registers or clinical risk management systems in hospitals [40]. To top that off, some knowledge sources like vigilance systems often provide information on different criteria or in different languages. Quality/ complaint management systems with computerized workflows will thus become most useful for the systematic processing and provision of post market data.

Limitations

Finally, we have to address a number of limitations. First, the study sample was deliberately chosen for data collection. In this way, manufacturers not organized in any of the three trade organizations mentioned above were excluded a priori. Second, the study was subject to the classic limitations of an online survey. For example, it could not be checked who responded to the questionnaire or if there were duplicate responses. Third, it should be noted that the manufacturers groups incorporated in the subgroup analysis were not equal in numbers according to company size and risk class, thus having a different impact on the overall means. The results can therefore only show a tendency among the company groups regarding the use of instruments and innovation potential. Fourth, the strict division between radical and incremental innovation possibly created confusion among the participants, resulting in a partly inconsistent classification. Finally, it is assumed that the participants of the survey were more likely employed by manufacturers with an experience above average regarding the internal transfer and use of post market knowledge. This would mean that the intensity of use of knowledge management instruments in daily practice is actually somewhat lower among the complete number of manufacturers.

CONCLUSIONS

Due to high pressure to innovate, medical device manufacturers are constantly faced with new challenges. We focused on the potential of post market surveillance, which has rarely been considered in scientific literature as a knowledge source for generating innovation impulses so far. The results show that manufacturers do not yet use the appropriate knowledge management instruments to its full potential. This may surprise, as an internal transfer of post market knowledge can promote the development of (especially incremental) medical device innovations and can thus indirectly contribute to the manufacturers' success. The transfer and use of device-related post market knowledge should be understood as a complementary Open Innovation approach for integrating external medical devices knowledge into R&D processes. Therefore we collected implications for enhancing the internal transfer of device-associated post market information between the post market surveillance and R&D departments.

The results can lead to multiple benefits for manufacturers, patients, users, and companies from other industries: Manufacturers may feel encouraged to use approaches and instruments for transferring and managing medical device-related post market knowledge and thus benefit from related opportunities and challenges to strengthen their innovative capacity for safe and effective medical devices and processes; this can in fact be a key differentiator for successful manufacturers in a highly innovative and competitive environment with limited resources, in particular for SMEs. Patients and users could benefit from this in every-day clinical care delivery. Last, but not least, the study results offer learning potentials for companies from other industries, particularly manufacturers of pharmaceutical and life sciences products.

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Conflict of interest

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Ethical approval

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Tab. 1: European risk classification system for medical devices [27], with device examples.

Risk class	Risk level	Medical device examples
I	Low	reading glasses, stethoscope, wheelchair, hospital bed, dressings, scalpel
IIa	Low-moderate	hearing Aid, blood pump, ultrasound device, MRI Scanner, contact lens, Positron emission tomography, dental implant
IIb	Moderate-high	intraocular lens, ventilator, infusion Pump, anesthetic machine, defibrillator, X-ray machine
III	High	Prosthetic heart valve, cardiac catheter, coronary stent

Tab. 2: Underlying typology of innovations, with description and examples from the medical device industry.

	Description	**Examples from the medical device industry**
Degree of innovation		
Radical	Major innovation that creates a new purpose/market and requires the application of a new technological principle or process	X-ray machine that initiated the market for diagnostic imaging
Incremental	Minor innovation where an existing product or process is further developed with already proven technological means in the sense of a continuous improvement process	Update of a specific software function, revision of a medical device guidance document, variation of an equipment part
Type of innovation		
Product/Device	Development of a (new) product/device giving a company the chance to increase sales and thereby secure or expand its position in the market	Drug eluting stent [30], da Vinci® System for complex surgery using a minimally invasive approach [31]
Process	Innovative production method to optimize internal processes so that products can be produced and offered in less time, to lower development and manufacturing costs, with less risk and/or at a higher quality	Improved transfer of medical device-related user knowledge between a company's medical consultants/field service and the internal quality and risk management department [32]
Clinical care process	Better way to apply a medical device by the user/patient in clinical care with the aim to optimize the use of medical devices on the market and, for example, reduce medical device-related complications or hazards	Improved approach for the safe use of an implant [33]

Tab. 3: Mean values and standard deviations of the self-reported frequency of use of the instruments for the internal transfer of post market knowledge between the departments for post market surveillance and R&D by instrument dimension.

Instruments for the internal transfer of post market surveillance knowledge	Frequency of use			Rank
	MV[*1]	SD (±)	Valid cases (n)[*2]	
Technology				
Groupware system/Email	4.2	1.4	115	1
Workflow management system	2.5	2.0	112	13
Complaint Management System	3.9	1.7	112	2
Document/content management system	2.8	1.9	111	10
Digital information/discussion portal	2.1	1.8	107	16
Knowledge/experience database, search engine	2.4	1.8	113	14
IT-based customer relationship management system	2.4	1.9	110	15
Organization				
Central anchorage of knowledge management	2.0	1.7	105	17
Knowledge manager/officer	0.9	1.5	108	20
Formalized knowledge storage	2.7	1.9	113	11
Formalized knowledge transfer	2.9	1.8	109	8
Idea workshops/management, quality circles	2.8	1.6	112	9
Informal communication channels	2.5	1.7	108	12
Knowledge balance sheet	1.1	1.5	103	19
Human Resources				
Willingness to share knowledge	3.1	1.6	112	7
Understanding of knowledge sharing by top management	3.1	1.4	102	6
Climate of openness and trust	3.7	1.2	110	4
Cooperative style of leadership, teamwork	3.7	1.2	107	3
Leeway for employees	3.5	1.2	108	5
Monetary incentives for knowledge sharing	0.8	1.2	96	21
Non-monetary incentives for knowledge sharing	1.3	1.6	96	18

MV, mean value;
SD, standard deviation;
[*1] MVs measured on a six-point Likert scale, denoting “unavailable” (0), “very rare” (1), “seldom” (2), “sometimes” (3), „often“ (4), „very often/always (5) respectively
[*2]Others stated „not specified“

Tab. 4: Mean values, medians, modes and standard variations for assessment of the potential of an internal transfer of post market knowledge for generating innovation impulses, ranking broken down by degree and type of innovation.

Rank	Innovations	MV[*1]	Median	Modus	SD (±)	Valid cases (n)[*2]
1	Incremental improvement of a medical device	3.9	4	4	0.9	117
2	Incremental improvement of a manufacturing process	3.4	3	3	1.0	117
3	Radical improvement of a medical device	3.0	3	3	1.3	117
4	Radical improvement of a manufacturing process	2.4	2	2	1.3	115
5	Incremental improvement of a device-related clinical care process	2.3	3	3	1.6	78
6	Radical improvement of a device-related clinical care process	2.0	2	1	1.5	81

MV, mean value;
SD, standard deviation;
[*1] MVs measured on a six-point Likert scale, denoting "never" (0), "very rare" (1), "seldom" (2), "sometimes" (3), „often" (4), „very often/always (5) respectively
[*2]Others stated „not specified"