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Importance of Knowledge in the Interdisciplinary Production Processes of Innovative Medical Tools

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***Abstract*—**Processes of production of innovative medical tools have interdisciplinary character. They consist of direct and indirect close cooperation of specialists of different scientific branches. The Knowledge they have seems to be important for undertaken design, construction and manufacturing processes. The Knowledge exchange between participants of these processes is therefore crucial for the final result, which are innovative medical products. The paper draws attention to the necessity of feedback from the end user to the designer / manufacturer of medical tools which will allow for more accurate understanding of user needs. The study describes prerequisites of production processes of innovative medical (surgical) tools including participants and category of knowledge resources occurring in these processes. They are the result of research in selected Polish organizations involved in the production of medical instruments and are the basis for further work on the development of knowledge sharing model in interdisciplinary teams geographically dispersed.

***Keywords*—**Interdisciplinary production processes, knowledge exchange, knowledge sharing, medical tools, user-centered design.

I. Introduction

IMPLEMENTATION of health services is related with the use of a wide range of equipment. Processes of treatment for many medical specialties are based on actions of physical impact on the body of the patient. This interaction is supported medical equipment automated and manual tools (e.g., surgical instruments). This is most evident in the case of such specialties as surgery, ophthalmology, dentistry, but also in the imaging laboratory.

Medical tools are a specific group of products, that support the processes of treatment and patient care. Quality related with reliability, ergonomics and exploitation is significant for the user (doctors or nursing). Errors (e.g. a lack of understanding between designer and end user) at the stage of design, construction and manufacturing processes of medical tools can lead to undesirable situations during treatment of the patient. This is disadvantageous situation for both parties (producer, healthcare organizations, doctors, patient etc.). May cause critical effects on both economic and social.

In Poland there are over 7,000 companies registered as medical equipment manufacturers [1]. Most are manufacturers of bioelectronic devices, operating theater equipment, rehabilitation equipment, furniture for medical facilities, equipment using medical imaging technology and surgical instruments.

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Previous research of authors was realized in department of trauma-orthopedic surgery. There, the subject of interests became surgical tools. Research about the shaping of working conditions [2] and the knowledge transfer [3], [4] in the hospital organizations, realized in 2006-2012, helped to note the problems within the aspects of utility of surgical tools. It became the reason beginning of the study on the broadly understood production and use of knowledge in their life cycle.

Literature confirms the need for continuous improvement of medical devices and tools [5], [6].

II. Background

The production processes are activities involving the processing of raw materials into finished products. The production process is the result of earlier stages, they are: design and construction. One definition of design is that it is a "conceptual preparation of activities". Result of this activity is the design as a formula desired object that allows its execution [7]. Dietrych distinction: *design* as an activity to devise the ways of satisfying the needs and *construction* - related with detailing the form of proposed object [8].

In the processes of design and construction of the product we can distinguish several characteristic phases. These are: identifying needs, developing the concept, developing a model / assigning traits, testing, economic analysis. For the effective implementation of such processes are required adequate resources. That's why the final product which is a tool or device is the result of work of interdisciplinary teams. The teams are grouped in their ranks of specialists in various fields of science who make direct or indirect cooperation.

Knowledge exchange between participants of production processes of innovative medical tools is crucial for the end result. The method and range of transferred knowledge have influence on participatory character of creating innovative medical equipment. The aim of this process is the design focused on the needs of the end user.

There are more and more publications about the research undertaken in the design and development of products and services focused on the needs of end users. [9]-[15] These studies focused on the processes and undertaken in these tasks required to achieve the intended purpose [16]. The aim of this is product (also service) that meets the expectations of the end user. This approach seems to be correct and it is consistent with the methodology called Design Thinking or User-Centered Design Thinking, Human-Centered Design or Development. But, if we consider the problem deeper, it is crucial to draw attention to the importance of participants and

the resources at their disposal to achieve the objective (including knowledge resources). This point of view highlights the nature of activities. Designing and development of product and services, taking into account the user's active participation in these processes requires the close cooperation between the involved persons. This requires a continuous exchange of knowledge between them. The knowledge of specialists of various branches is not always understood by the other participants [5]. This contributes to a longer processes of shaping finished product which enough fulfill the established criteria. It seems reasonable to analyze the importance of individuals' cooperation in often geographically dispersed interdisciplinary teams in production processes of medical tools (from design to finished product).

III. Types of Knowledge on the Background of Interdisciplinary Nature of Production Processes

Establishment of interdisciplinary teams responsible for the production of an innovative product is complex and involves several steps. One of them is the selection of experts having the relevant competence and level of knowledge required to solve the problem or achieve the goal. This stage in itself requires knowledge about organizing and leading such a group. Manufacturers of medical equipment in Poland does not have such teams on a permanent basis. They are organized ad hoc, as part of a specific task / project, e.g. in the form of a research project or implementation project. The subject range and objective evidence of designing and construction decide which areas of science the specialists should represent. Assuming that the product must meet user expectations, he must have an input into its development. Design Thinking methodology [15] implies a deep understanding of the problem, multidimensional approach to the problem, experimentation and the need feedback from the user.

In the case of development initiatives or the creation of innovative medical devices (which may be surgical tools) essential are objective evidence to being an impulse to start work. On the Polish market initiators of processes to create innovative products are: users (certified doctors), manufacturers, and scientific and research and development units (R&D).

Users initiate the process of creating a new product as a result of their experiences with medical equipment which is in the organization. In the course of treatment and patient care processes (e.g. Surgery), they note the imperfections of products. Practical use of tools in a hospital environment, under real conditions, taking into account the many recurring medical cases, various diseases and human anatomy, auxiliary processes (e.g. Sterilization) shows the advantages and disadvantages of products available on the market. Observations show that such evidence is rare. Problems related to usability, ergonomics and quality tools, do not go beyond the operating room. Doctors are not satisfied with the available products, but also do nothing to improve these products. They feel that they have no influence on it. This is contrary to the adopted by the manufacturer Design Thinking methodology.

The second case is initiating work on innovative medical instruments as a result of research and development within the organization. This is the case when the producer in its structure has a research and development department aimed to recognize the needs of the market, new technologies, new materials, information on medical breakthroughs. This situation requires the acquisition to the team first and foremost a specialist - the user, who will act as a consultant, tester, an intermediary between the medical community and technical.

The third premise is notification of the need on the part of universities and R & D institutes outside the organization. Institutes as a result of research want to deploy the product on the market, start cooperation with a specific manufacturer, who holds the necessary resources to meet the criteria set out. In this case, the construction of an interdisciplinary team begins inside the R&D institution, which at the stage of research projects is building a potential working group. The implementation work to develop a group of additional members.

Each of the conditions causing activity in the area of creating innovative medical devices requires appropriate human resources, possessing specialized knowledge resources and are able to communicate with each other. The communication is often impaired process. This is the result of human factors and applied communication channels. Teams are built with members which every day working in different organizations (scientific, medical, manufacturing, commercial, economic, etc.) scattered geographically. The territorial scope of the teams may be national and international.

Employees of the organization are both a source and media of knowledge.

As indicated by [17], the total of knowledge of organization consists of the sum of the knowledge of individual employees and teams of employees, data and information, on the basis of which is built individual and collective knowledge. It is assumed that each team member has professional expertise. This knowledge can take the form of general knowledge and the subject knowledge, explicit and tacit knowledge.

General knowledge is considered as the basic in the field of reality. Moreover, it is generally available and formally recorded.

Subject knowledge (specialized, thematic) is defined as knowledge acquired as a result of many years of experience and is associated with individual human skills. It should be noted, that for any subject knowledge can distinguish the permanently and renewable components.

Permanently components of knowledge are understood as those that regardless of the emergence of new ways of thinking, new methods, techniques and technologies remain the same (e.g. Human anatomy).

Renewable components of knowledge are those who, due to changes occurring in the area of interest of the organization need to be updated. An example of forcing an update elements of knowledge are inter alia innovation in the field of pharmacological treatment (e.g. new vaccines), innovation in the area of physicochemical properties of dressing materials, use of modern technology (formerly the introduction of

electronic patient card or the use imaging using X-ray), the use of new equipment and medical instruments (e.g. the instruments to implement procedures), personnel changes.

In the context of reflection on knowledge in the interdisciplinary production processes, there was made a division of knowledge by its form into:

Explicit knowledge - which is characterized by ease of access, codified in the form of generally accepted knowledge media (paper documentation, procedures, manuals, computer systems (e.g. an electronic patient record), specialized web portals;

Tacit knowledge - to which access is not direct but occurs through asking questions, for discussion and observation of human behavior in the possession of knowledge. This is codified knowledge. Tacit knowledge includes a generally held knowledge and skills of doctors, nurses, technical and administrative staff, manufacturers in the delivery of official duties - knowledge about usage of surgical instruments, how to assemble and disassemble surgical instruments, knowledge of production processes, maintenance of the machinery and so on.

Such a division of knowledge can help recruit the members with the most current knowledge in their field. This will affect the realizing the interdisciplinary processes.

Interdisciplinarity brings advantages and challenges to be overcome to cooperation between team members was effective. Thus, the exchange of tacit knowledge is becoming a challenge in the way of shaping innovative products. Acquisition of knowledge from the potential or current user is important for the proper conduct of the design and construction phase. In the process of a design and construction of the product we can distinguish several characteristic stages. These are: identifying the end user needs, developing the concept, developing a model / assigning traits, testing, economic analysis.

To the various steps involved are individual employees. The Interdisciplinary Working Group (IWG) working on innovative medical instruments include analyst, engineers (designer, constructor), manufacturing specialists, medical specialist, economist / manager, marketing specialist, sales specialists. Fig. 1 shows a sample list of members of the interdisciplinary group working on innovative medical devices taking into account the initiators of the process. The essence of this cooperation is to exchange knowledge and experience within the specialty of individual members. The Group operates within the organization that initiated the work (production companies, medical organizations, D&R companies). Members can be dispersed geographically.

Fig. 2 illustrates a graphical diagram of relationships in the interdisciplinary process. Imaging the avenues of cooperation and interaction allows us to understand how wide is the range of knowledge needed to create a single product.

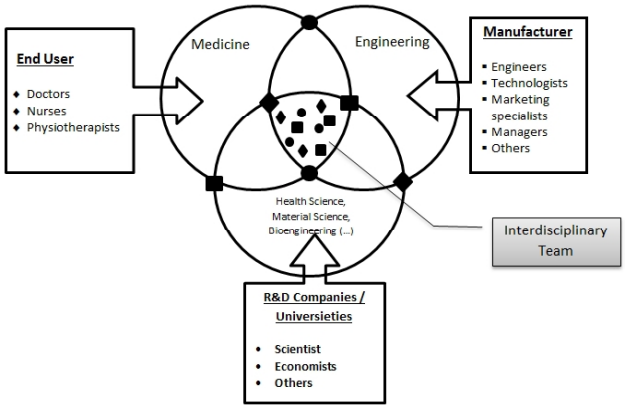

Fig. 1 Sample list of members of the interdisciplinary group working on innovative medical tools

Circles on Fig. 2 symbolize individuals, the arrows indicate the ways of direct and indirect collaboration / knowledge exchange.

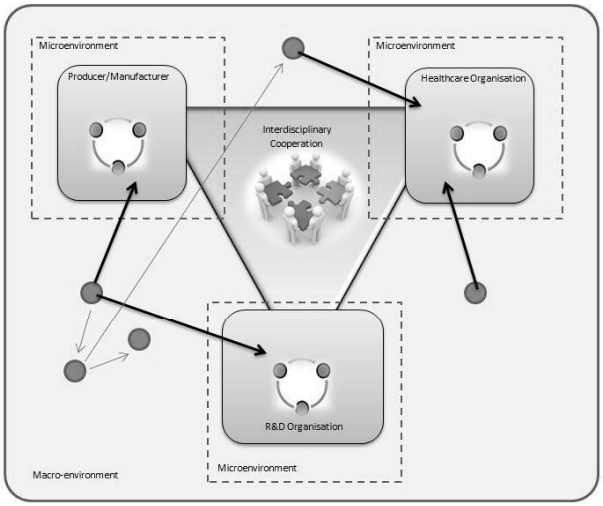

Fig. 2 Scheme of collaboration between participant of the medical tools production process

Each individual person, working on the finished product has a specific knowledge (general, subject, explicit, tacit). The total of knowledge of individuals is not equal to the collective knowledge. *Individual knowledge* is understood here as the sum of general knowledge and expertise codified or not held by the employee. *Collective knowledge* is accumulated in the procedures, standards, rules, but also beliefs, convictions, views allow group collaboration. Collective knowledge may have a higher value, or lower than the sum of individual knowledge. The difference is the result of methods and willingness to cooperate various individuals, which care about their competitiveness and autonomy in spite of a common goal. Each specialist wants to emphasize its importance and the need for cooperation. Knowledge is invisible resource, which is responsibility for success in the action taken.

IV. Importance of Knowledge in Stages of Production Processes

A. Materials and Research Methods

In this paper author shows the results prepared on the base on own research in qualitative nature. The subject of the research included: identification and analysis of participants of production processes of innovative medical tools, which were surgical tools (e.g.), recognition of the knowledge resources at the disposal of participants in the process, analysis of importance of knowledge on the stages of production process.

Used qualitative research techniques, like:

1) Casual interviews, partly categorized interviews and observations - in side of the participant identified as a producer interviews were conducted with the tools bone surgery designer, a distributor and owner of a factory of surgical instruments. In side of the user interviewed were conducted with: orthopedic surgeon, scrub nurses, employee from department of tools sterilization.
2) Analysis of internal documentation including manuals surgical techniques, manuals, catalogs, register of sterilization process etc.
3) Analysis of the information contained on the websites of Polish manufacturers of medical product in the organizational structure.

B. Knowledge Resources in Stage of Production Processes

Analysis of the structure and activity of Polish manufacturers indicated that they activities are multi-stage.

Companies rely on many years of experience in the industry and emphasize cooperation with healthcare professionals, hospitals, universities and research - development. The emphasis on cooperation with external units a more or less conscious stresses the need for the exchange of knowledge between individuals of different industries. In addition, targeting due to the many years of experience reveals that knowledge is a key factor / resource to develop a good product.

The interviews made in one of Polish producer of surgical and dental tools have allowed to identification of categories of knowledge required to production processes.

Table I include lists of categories of subject knowledge (understood as "know what") assigns to groups of users involved in the production.

Knowledge resources intermingle, and they are the subject of exchange. They are also the base of decision-making processes, which should be considered from many points of view [18]. Increasingly, organizations are aware of the profits arising from the possession of specific knowledge, but also the lack of benefits due to limited resources. Note, however, that tacit knowledge is difficult to transfer. However, there are methods to codify tacit knowledge to accumulate in cognitive and practical purposes [19].

There was defined the qualitative character of the benefits and effects arising from the application of the knowledge in manufacturing of surgical instruments. Table II summarizes selected resources and their influence on activity of the manufacturers.

On the way the use of knowledge in the production of tools standing barriers related to the exchange of knowledge. Lack of clear criteria and guidelines of cooperation, lack of adequate tools for the clear wording gained from experience compounded the problems. Among the team members there is distance to act, which is the common goal and reach a compromise.

TABLE I
Categories of Knowledge in the Production Process of Medical Tools

Category of knowledge	Producer	Healthcare Organization	R&D Company / University
Medical Knowledge	Ergonomic knowledge;	Knowledge about available treatment techniques; Medical biomechanics;	Knowledge of innovation in the medical industry, including new medical work techniques;
Engineering Knowledge	Knowledge about materials; Knowledge of technologies; Knowledge of the production capacity; Knowledge of production facilities; Knowledge of methods of design; Knowledge of the physicochemical phenomena; Knowledge of computer-aided design tools; Knowledge of service;	Knowledge of methods and work space; Engineering biomechanics; Knowledge of the advantages and disadvantages of products available on the market;	New solutions in equipment area; Knowledge of innovation in the technology industry, e.g. new processes, new measurement methods; Knowledge about possible applications of materials and technologies in special conditions;
Administrative and Management Knowledge	Knowledge about the economics of production;	Knowledge of the principles of financing health care organizations;	Knowledge about the possibilities and rules for participation in research and implementation; Knowledge about the possibilities of science financing;

TABLE II
LIST OF SOME BENEFITS AND CONSEQUENCES ARISING FROM USE OF OR NOT APPLYING AN INTEGRATED, INTERDISCIPLINARY KNOWLEDGE FROM THE PRODUCER POINT OF VIEW

Knowledge resources	Benefits	Consequences
Advantages and disadvantages of products available on the market	Benchmarking; Development of product; Learning from the mistakes of others;	Duplication of design errors;
Knowledge of methods and work space;	Designing the characteristics of product to it fits into the work space Selection of material properties meet the requirements of specific conditions (including maintenance, e.g. for sterilizing purposes) ł	Defectiveness of product; User dissatisfaction; Limited durability;
Knowledge about available treatment techniques	Assigning of characteristics of construction, such as: the dimensions, forces, assembly and disassembly methods to the real conditions;	Useless of product; User dissatisfaction; Limited durability;
Knowledge about human anatomy	Assigning of characteristics of construction, such as: structure, the need to use additional supporting elements, selection of materials which have contact with body	Useless of product; User dissatisfaction; Bodily injury;
Knowledge of new materials and raw materials	The possibility of product improvement by changing the design characteristics (lightweight, tools ergonomics, resistance to sterilization processes, resistance to biological factors)	Obsolete materials; Lack of competitiveness on the market; Drop in sales; Problems with service;
Knowledge of new production techniques	Development of new products in terms of technology; Minimization the time and cost of production; Increase capacity of production; The possibility of processing new materials; Increase competitiveness;	Inability to use new materials; The lack of product development; Design constraints;
Knowledge about the possibilities and rules for participation in research and implementation;	The ability to obtain financing for the expansion of the machine park; The development of production; Increase competitiveness;	Alternative costs (explicit costs);

Using of knowledge in the production of medical tools is limited, what is the result of barriers related to the exchange of knowledge. Another factor affecting adversely the form of cooperation is the territorial dispersion, human barriers (e.g. Language) and the necessity to generalize needs due to the large group of target users.

The need to develop tools supporting methods of expressing, coding of knowledge for unambiguous interpretation of views of each participant is then justified. The starting point is to try to develop clear standards for individual participants in the design and construction process. The idea is that a tremendous amount of knowledge gained should be selected and skillfully use it to achieve the intended purpose. In the case of the production of innovative medical product, the main objective is a tool. This product may indirectly affect the achievement of the objectives of the organization. Both the manufacturer and other members of the interdisciplinary production define specific objectives, which are: financial gain, low production costs, low costs of healthcare processes, high quality products and services, customer confidence, satisfaction of employees and patients.

V. CONCLUSION

Considerations on the importance of knowledge in the implementation of organizational processes (both main and secondary) show that the skillful use of the resources of knowledge allows you to build a competitive advantage in the marketplace and strengthen the position of the organization. These issues relate to the use of knowledge. Entrepreneur / Producer aware of the importance of having knowledge resources is able to acquire, collect, organize, share them and use, which means manage these resources. Rational management of knowledge allows you to transform them into sustainable value for the company, employees and customers. Benefits and consequences may be measurable, indicating profits and opportunity costs. The author plans to continue research on the analysis of the benefits (including measurable benefits) resulting from the application of interdisciplinary knowledge at every stage of the production process.

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