

"In the same Boat" – Considerations on the Partnership between Healthcare Providers and Manufacturers of Health IT Products and Medical Devices

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Summary

Objectives: To assess the current culture of cooperation between healthcare providers (HCPs) and the healthcare industry (HCI) in the domain of Health-IT and Engineering (HITE) and identify possible strategies for improvement.

Methods: Based on reports in the literature and personal experience, major challenges were identified, the current ways of cooperation defined and their relation to each other analyzed.

Results: Four main challenges were identified for both sides involving: products and functionality, integration of IT-Systems with each other and with medical devices, usability, visions and strategic management. None of the four defined cooperation categories cover all aspects of the challenges, but cooperation in small, dedicated groups appeared to provide the most advantages. An increased participation of HCPs in standardization activities is crucial either directly or indirectly via professional or scientific organizations.

Conclusions: Cooperation between provider management (hospitals, clinics or systems) and manufacturers of health IT products will be the key factor for success of the HCI while providing substantial benefits for providers. Both sides should invest heavily in such efforts.

Keywords

Cooperation, health-IT and medical engineering, public-private-partnership, standardization

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Introduction

For all Healthcare Providers (HCPs - taken as organizational entities like hospitals, clinics, or regional/national health systems), tight cooperation with the Healthcare industry (HCI) and in particular the Health-IT and Engineering (HITE) manufacturers is an essential task. The scope here is to identify main challenges from the HCP viewpoint and analyze how they are addressed by the current types of HCP-HCI cooperation which are categorized for this purpose. Special attention is given to the different stakeholders and user groups within HCP organizations.

Challenges from the Healthcare Providers (HCPs) Point of View

Based on personal experience and references four main areas were selected where an intense cooperation with the HCI has to be considered essential or strongly desirable and where deficits could be identified. For a useful analysis the user groups (UG) within HCP organizations have to be differentiated. Seven types are relevant for the present investigation: 1) average clinical end-user, 2) clinical user application specialist, 3) HITE department application/equipment specialist, 4) HITE department systems integration expert, 5) HITE department infrastructure expert (networking, operating systems, security), 6) HITE department executive level (IT or ME department head, CIO) and 7) clinical executive level (department chair, head physician or nurse). The challenges are sorted according to

their frequency of occurrence and assumed strategic importance.

Challenge 1: Product functionality and quality

There is clear evidence that many existing Healthcare Information systems do not suit the users needs, and is considered a main obstacle to their wider adoption [1,2]. This challenge is critical since the deficits reach far beyond marginal weaknesses but are instead major in nature. Two different types of challenges can be differentiated: when a functionality or module is either missing; or when existing designs or modules only partially provide the required functionality or support the desired workflow. The important issue with the latter is to reach a high degree of concreteness and specificity in the functional specifications and to avoid too many losses in the transition from design to the implemented product [3]. Evaluation studies [4] have demonstrated that especially the UGs 1-3 are crucial for this process, but they have to be supported by all other UGs. Hence cooperation has to put on a very broad basis.

Challenge 2: Integration of IT-Systems with each other and with Medical Devices

As of today hardly any IT architecture is completely monolithic. Hence systems integration almost always requires involving different manufacturers. In this situation the HCP often becomes the moderator communicating with and between the involved industrial parties trying to accomplish the integration ideally by employing standards that are responsive to the needs of quality healthcare delivery [5]. When referring to intra-institutional systems, integration standards are well accepted, and in wide-spread use. On the other hand for cross-institutional

integration, especially when involving different kinds of HCP and different types of IT-systems, integration and hence communication in order to achieve it is invariably a tremendous challenge [6,7].

One recent trend which could have a major impact in the future, is the alignment of HIT and ME. This applies to both, intra-institutional and cross-institutional integration approaches. The intra-institutional approaches integrate medical devices into clinical networks and applications in order to complement electronic patient records, streamline workflows and avoid disruptions [7,8] while cross-institutional initiatives support integrating, for example, Personal or Electronic Health Records (PHR, EHR) with home monitoring solutions and sensor devices as well as AAL solutions (ambient assisted living) [10,11,12]. This is reflected on the organizational side by an increasing number of hospitals that are either combining the IT and ME departments or at least fostering cooperation between those units. In parallel it could be observed that major medical device manufacturers have acquired IT companies with HIT solutions and more and more engineering SMEs (small and medium enterprises) develop and include IT solutions in their portfolio or liaise with HIT manufacturers. Those developments have two main implications: a) integrated solutions are still under-developed or subject to future developments and b) we are entering a new era when risks occurring in the IT-environments from unsafe medical devices (e.g. viruses, worms etc.) and for the medical devices resulting from their integration into networks (also virus infection as well as, for instance, galvanic separation) can easily become exacerbated. Both areas require much closer user-manufacturer cooperation, involving in particular competencies from UG 3-6 being supported by UG 2 and sometimes UG 7.

Challenge 3: Usability

The main user groups of HIT-systems and medical devices are doctors and nurses. They are not full-time users but spend only limited amounts of time per day with the IT systems and machinery, so improper usage, especially in the latter case, may be life threatening [12].

Hence one would expect that usability engineering would be an essential pillar of product design [14] to (i) improve end-user's satisfaction and effectiveness by simplifying use, (ii) reduce healthcare errors, and (iii) improve efficiency by optimizing procedures in clinical workflow. However a solid and formalized engineering process involving end-users (including usability labs and standardized methods) is still not commonplace technological practice today [15,16]. Ideally this approach would be combined with rapid development and feedback cycles and the UGs 1-3 must be brought into the process of device and HIT-system evaluation as early as possible to articulate their opinions ahead of time so as to better judge and provide feedback on design use in clinical contexts based on expert hands-on experiments.

Challenge 4: Visions and strategic developments

Beyond the regular product development cycle, the HCPs user groups develop visions and strategies, varying from concrete implementation proposals to vague ideas for new solutions. A HITE-strategy requires knowledge of the following domains: end user needs, product capabilities and limits on all layers from networking to the application level, existing standards with their capabilities and deficits, companies' properties and economic situation as well as market developments and trends. Although some people may oversee all such domains, it would be better to establish tight cooperation between the UGs 6 + 7 within the HCP. Together they will unite all core competencies with the necessary breadth of vision, coupled with a sufficient depth of experience in the components. They require equivalent partners on the HCI side in order to share their visions. When the HCI partner has internally-managed cross-product-line cooperation, one can expect that effective, coherent visions and solutions can be jointly developed. The issue here is to find the right level, mix and platform for this cooperation.

Reviewing all the above described domains it becomes evident that none can be addressed and solved in a short time frame. All require long-term partnerships with a high degree of long-term com-

mitment and mutual trust, which are often complicated by frequent changes on the industrial side. This challenge has to be urgently addressed in order that lasting and fruitful partnerships will flourish.

Current Categories of HCP-HCI Cooperation

In the past classical medical device manufacturers were mainly talking to their clinical users (UG 1,2 and 7) in order to improve product functionality, whilst IT companies were communicating in addition and mainly with the IT departments (UG 3-6), which is considered a major impediment [1,4]. With the upcoming tighter integration of HITE this has changed, and today clinical end-users as well as clinical IT departments have to be considered equally important for all developments. In general, the following approaches may be found either as single paths or in various combinations with each other.

Category 1: One manufacturer with one HCP

This is perhaps the most frequent setting. Three main phases should be differentiated: procurement, implementation and roll-out, and continued development. When procuring a new HITE solution the process should ideally start on the HCP side alone with a high-level discussion involving UG 6 + 7 in order to develop a joint vision. In a second step the drill-down into the requirements engineering would involve all HCP user groups. Unfortunately this is often not the case and clinical users (UG 1,2,7) are first introduced when the project enters the implementation phase. However, leaving clinical users with their specific experience in what might or might not work out of the specification and procurement process typically leads to major mismatches and unsatisfactory HIT systems. The principal problem here is that, unless it is a replacement project, no UG of the procuring organization has real in-depth knowledge or experience with respect to the product to be procured so that a high degree of concrete-

ness and specificity is unlikely to be achieved. Apart from the lack of knowledge, the time in order to produce solid specifications is often limited. Both elements lead to imprecise requirements which can then not be properly answered by the HCI causing misunderstandings and unsatisfactory results. The only solution is to proceed stepwise. The HCP user groups 1-5 have to conduct all steps jointly in order to learn from each other. They have to invest time, which has to be granted by the executive level, for market explorations, site visits, demonstrators, and pilot implementations in order to produce solid specifications facilitating the HCP-HCI cooperation substantially.

Once a product has been rolled out, the continuous development process is often cumbersome since manufactures have their established road-maps and are rarely keen on including new requirements after having fulfilled their contractual obligations knowing that the HCP is bound to their system. In addition, joint specification projects are typically considered with great reticence from the manufacturer's side due to the inherent risk of customer-specific configurations which may have little or no general applicability and future market value. This is a key issue in today's HCP-HCI cooperation culture, missing substantial opportunities. Once both sides learn to respect their particular demands they can enter into a truly mutual cooperation which is certainly an ideal vehicle to address all the Challenges, but in particular 1 + 3 in order to achieve the best possible products and improved usability. HCPs have to learn to think more entrepreneurially in balancing their own specific needs to those of the manufacturer and systems developer, and to identify opportunities in their clinical context that could be generalizable to broader and even international clinical needs. Only in this way can they become full partners in the HCP-HCI cooperative process.

Category 1b: One HCP with multiple manufacturers

This situation occurs in all systems integration projects involving multiple companies and hence very frequently. Most

of what was said for Category 1 is identically applicable apart from the fact that UG 3-6 are affected intensely. Depending on the individual interests of the manufacturers involved, this can be very successful and provide substantial input to Challenges 1-4, or very cumbersome and ineffective. In the latter case the only option from the HCP side is to stick to the standards and abstain from any hope of going beyond that!

Category 2: One manufacturer with a limited number of HCPs

One example within this configuration is advisory boards. Depending on the original intention of the manufacturer, advisory boards differ in size and composition and are usually invitation-based. They focus on the UGs 6 + 7 of various HCPs and are mostly put together on an international basis in order to discuss the strategic positioning and development of the company's product portfolio. However, as the size of an advisory board increases, it usually changes in nature. Small advisory boards have the ability and desire to provide serious insight into a company's strategy and expect their input to be taken seriously, while larger advisory boards often become mere rubber-stamps for predetermined management plans and serve more as a customer relationship cover for them. Despite this, when selected with serious feedback in mind and not too large, executive advisory boards can be an excellent platform to achieve valuable input for a shared vision and hence to address Challenge 4 and partly 1 but are unsuitable for Challenges 2 + 3. Challenges 1-3 are better addressed with peer groups. Depending on the Challenge, members of UGs 2-5 may be selected. When combined with Category 1 this approach allows a good degree of concreteness and at the same time can avoid too many user-specific solutions and is hence a very powerful addition when enough time is dedicated to it.

Category 3: One manufacturer with multiple HCPs (user groups)

User groups may be initiated by the HCI as well as by the HCP. They are usually national, meeting once or twice a year

and assembling mainly staff from UGs 2 + 3. In the majority of cases, user group meetings are devoted to the presentation and discussion of a new functionality, or to provide outlines of future developments of the manufacturer. Although exceptions may exist, user groups are, due to their size, unsuitable for concrete and focused cooperation in the sense of Challenges 1-3 but they may provide some help for Challenge 4. Those national requirements have to be internationalized by the HCI in a second step. Also, the pluralistic nature of Category 3 is both an advantage and disadvantage, since it avoids extremes in both directions.

Category 4: Multiple manufactures with multiple HCP

This configuration usually comes up as part of standardization activities. Apart from some quite successful examples (HL7 and DICOM) the majority of standardization group is dominated by industrial participants and consultants. Delegates from HCPs are usually in the minority and if present, represented on the expert level from HITE departments (UG 3-5). A systematic representation by either medical informatics or health IT associations is also not seen too frequently. However, current standardization activities dealing with the integration of medical devices into clinical networks (IEC 80001) [17] foresee intense HCP-HCI collaboration and hence a strong user voice is essential in order to avoid imbalances. The main problem from the user's perspective, against common expectation, tends not to be the financial aspect, but time issues. Standardization is time-consuming it is difficult for users to participate with a comparable intensity as on the industrial side. In order to improve the current situation, some possible measures need to be considered: (i) the fact that standardization is a key issue in today's HITE has to be brought to the hospital director's board. They have to understand the importance and allow their highly qualified staff to dedicate resources to it. In order to achieve this, the message has to be spread simultaneously by customers and manufacturers and strongly supported by public authorities as well on a national as on an international level. It is evident that

this is a long term process, but it is essential and should be mandatory; (ii) the professional organizations should take a more active role and send delegates in order to empower the voices of individual user participants, and in parallel actively approach the hospital boards of directors in order to support the above-described process; (iii) even with this strong push towards user participation, it is unlikely that the imbalances will be remedied in the near future. Hence, the decision processes and voting principles within standardization committees should be modified in order to give a stronger vote and perhaps even veto rights to the clinical-user participants which can be supported and achieved by feedback from their respective professional organizations.

This area of cooperation area may help tremendously in addressing Challenge 2 but its impact can be negligible for the other Challenges when restricted to standardization alone. However, this scenario would also apply to multi-partner research and development projects with external funding or grants, but a detailed description of those elements is beyond the scope of this paper.

Discussion and Conclusions

The comparison of challenges and cooperation across categories reveals that the most common Category 3 (user groups) is also the most inefficient in addressing requirements. On the other hand Categories 1 and 2 can be beneficial for almost all challenges although with different user groups. For Challenge 1 + 3 it is essential that average end-users as well as clinical and HITE application specialists are present and mix adequately. Skilled clinical application specialists (UG 2) are of tremendous importance for this process but usually these people are rare. Therefore HCP have to set up education initiatives to develop and establish „key user“ concepts and consider this a project of strategic importance. But for Challenge 4 it is preferable to combine the clinical (physicians and nurses) with the HITE executive level. Only for Challenge 2 a sole representation by the HITE department ap-

pears feasible. A very high frequency of cooperation is recommendable for Challenges 1 + 3 and a regular rhythm with interim hands-on status reviews should be planned, whilst Challenges 2 + 4 can be addressed in a more loose fashion.

It can be assumed that the HCI shares the challenges with the HCPs although their motivations are different, and additional aspects have to be considered. In principle the vendor's motivation is to address the customer's needs by providing a unique solution to the market, superior to the competition, with the prospect of financial success. HCP users acknowledge that vendors therefore have to balance the following: (i) national and international needs, (ii) different users using the same system, (iii) diverse workflows. Additionally, limited resources, technology risks, and pressure for implementing shorter time-to-market may influence or hinder the envisioned results. But still the users are the real champions in all three areas mentioned; hence it is likely that the closer the HCI cooperates with the HCPs, the closer they are likely to achieve their original goals. Companies investing in close cooperation play smarter than the competition, and will have a superior market position, and develop unique selling points. On the other hand HCPs will obtain the products they desire. This issue is likely to be critical to the future development of the entire HITE market. One paper cannot hope to provide a complete overview and discussion of all aspects associated with the cooperation between HCPs and HCI in developing HITE products. Instead, the main objective here was to raise awareness that the only way to create win-win situations is to invest in partnerships.

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