

Title: The EAES intellectual property awareness survey

Running head: EAES IP awareness survey

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## Abstract

**Introduction:** The protection of intellectual property (IP) is one of the fundamental elements in the process of medical device development. The significance of IP, however, is not well understood among clinicians and researchers. The purpose of this study was to evaluate the current status of IP awareness and IP-related behaviours amongst EAES members.

**Methods:** A web-based survey was conducted via questionnaires sent to EAES members. Data collected included participant demographics, level of understanding the need, new ideas and solutions, basic IP knowledge, e.g. employees' inventions and public disclosure, behaviours before and after idea disclosures.

**Results:** 179 completed forms were obtained through an email campaign conducted twice in 2019 (response rate = 4.8%). There was a dominance in male, formally-trained gastrointestinal surgeons, working at teaching hospitals in European countries. Of the respondents, 71% demonstrated a high level of understanding the needs (frustration with current medical devices), with 66% developing specific solutions by themselves. Active discussion with others was done by 53%. Twenty-one per cent of respondents presented

their ideas at medical congresses, and 12% published in scientific journals. Only 20% took specific precautions or appropriate actions to protect their IPs before these disclosures.

**Conclusions:** The current level of awareness of IP and IP-related issues is relatively low among EAES members. A structured IP training program to gain basic IP knowledge and skill should be considered a necessity for clinicians. These skills would serve to prevent the loss of legitimate IP rights and avoid failure in the clinical implementation of innovative devices for the benefit of patients.

**Keywords:** intellectual property, invention, patent, public disclosure, employees' invention, medical device

## **Introduction**

The successful development of medical devices relies not only on well-screened unmet needs, production design, prototyping or engineering efforts but also on preclinical/clinical evaluation, regulatory processes, marketing and business model [1] [2] [3]. The protection of intellectual property (IP) is also one of the fundamental elements in the process of medical device research and development (R&D) [3]. Without adequate IP protection and management, most "clinician-derived" medical innovations will not advance into the real R&D phases, resulting in failure of clinical implementation for the benefit of patients.

However, the importance of IP rights (IPR) is not well understood among clinicians [3]. Even translational researchers at academic institutions are not always familiar with IPR. Consequently, a substantial amount of ideas and solutions have been either inadvertently shared globally or have been "frozen" by the competitors in an effort to protect their own medical products. These factors potentiate a loss of clinical implementation of new medical devices [3]. In general, the development process of new ideas potentially improving current medical devices or even a novel idea for a new device is composed of multiple steps requiring time and funding. Patent rights are crucial in order to enable commercial release and economic benefit of any new device. In the case of public

disclosure, for example, of the new idea in a medical journal or conference, this idea turns into public knowledge and a patent can no longer be obtained. In this case, development efforts and production of the device would not result in a financial benefit, and companies would then refrain from adopting the new technology.

As active technology committee members of the European Association for Endoscopic Surgery (EAES), the authors believe that any innovative ideas and solutions from our fellow members potentially contain IP, therefore, should be appropriately protected. Before organizing an IP awareness enlightenment or training program, we decided to conduct a comprehensive survey to determine a baseline regarding current IP awareness before course development. This study aimed to evaluate the current status of IP awareness and IP-related behaviours amongst EAES members, i.e. medical professionals and translational researchers, via a web-based questionnaire survey.

## **Methods**

An "IP task force" was formed by the technology committee of EAES on June 11, 2019, in Sevilla, Spain. The task force members included 10 surgeons and 6 bio-med-tech engineers. Our goals were: 1) to share essential knowledge of IP among EAES members, 2) to

transmit necessary information and skills to raise their IP awareness, and 3) to discuss and organize possible IP awareness training programs for members.

The basic concept of the IP survey was proposed at our first meeting. The methodology of the survey, as well as question content, was discussed and finalized by September 2019. The actual survey was initially planned to start on a web-based platform and to be complemented by in-person interviews during the 2020 EAES annual congress in Kraków, Poland. However, the face-to-face interview turned out to be impossible due to the worldwide pandemic of COVID-19 in early 2020. As a result, the survey was conducted totally on a web basis, i.e. sending emails with the URL of survey administration software (Google Forms, Google LLC, CA, USA) to all EAES members.

An outline of the survey is shown in Fig. 1. Each participant logged into the dedicated survey website provided via Google Forms, using the URL supplied to them by the EAES executive office sent to his/her registered email address. In total, 28 questions were set up with either single or multiple-choice forms or free entry sections. Data was requested regarding 1) demographics (age, gender, subspecialty, work location, country, work experience); 2) any experience with unmet needs, e.g. new ideas based on frustration with current medical devices, 3) existence or non-existence of institution-specific IP/tech



transfer office, 4) disclosure of new ideas, 5) preparation for idea disclosure, 6) response of discloser, and 7) any experience relating to patent application. The additional questions are listed in Appendix A. All answers were compiled, and the numbers were tallied up on a Google Form.

## **Results**

The email campaign was initially launched in October 2019 and repeated in November 2019. The emails were successfully delivered to 3,728 and 3,719 members, respectively, and eventually, 179 completed forms were obtained (response rate = 4.8%). The survey program was closed in January 2020, and the results were shared and discussed among committee members thereafter.

Table 1 shows the background data of survey participants. There was a dominance in male (91%), medical doctors (99%) from European countries (79%). The age and clinical experience distribution suggested that most of the responders were formally-trained surgeons, with 96% identifying as gastrointestinal surgeons. More than two-thirds of respondents were employed in teaching or university hospitals.

Table 2 illustrates the frustration with current medical devices, and how surgeons shared their new ideas and what, if any, other steps they took regarding solving said unmet needs. Most surgeons (71%) felt frustrated with current medical devices, and 66% of them came up with specific ideas to solve their frustration. Being unaware of the significance of the potential repercussions, 54% discussed their ideas with sales representatives from industries, 53% with their colleagues and 38% with their mentors. Additionally, 21% presented their ideas at conferences in scientific sessions, and 12% presented at invited or booth talk sessions. Finally, 12% published their ideas in scientific journals.

Before public disclosure of their ideas, only a handful of surgeons took precautions, as demonstrated in Table 3. Precautions included such actions as consultation with the institution's IP/tech transfer office (20%) or external supporting office (8%). Only 18% of ideas had patent applications for their ideas before abstracts submission to congresses or journal manuscripts. Non-disclosure agreements (NDA) were signed in a mere 15% of cases. The remainder (59%) took no precautions or actions before the disclosure of their new ideas in a public forum.

Table 4 summarizes the reasons why surgeons refrained from taking any action for their new ideas (25 responses). Half of them argued they were "too busy", 36% expressed a

lack of knowledge regarding the appropriate time and place for idea disclosure. Other reasons provided for lack of precautions included "I thought my idea was not interesting" (36%), "I was afraid of too many troubles ahead" (20%), "I was afraid of expenses" (12%), and "I was afraid people would make fun of it" (12%).

Table 5 shows the post-analysis comparison of IP-related activities between "strong IP awareness" members who correctly recognized the existence/non-existence of institutional IP/tech transfer office ( $n = 113$ ) and "weak IP awareness" members who were unaware of their existence ( $n = 66$ ). While both groups showed a similar level of frustration (needs consciousness) with current medical devices, the strong IP awareness group had a significantly higher number of members who reached specific solutions for new devices by themselves, as compared to the weak IP awareness group (72% vs 53%,  $p = 0.04$ ). The strong IP awareness group also attracted more interest from the industry as compared to the weak group (66% vs 37%,  $p = 0.03$ ). Interestingly, there were no differences in "precaution prior to disclosure" and subsequent "careless disclosure" between the two groups. While the number of members who had patents in their name tended to be higher in the strong IP awareness group, this was found to be statistically insignificant (38% vs 20%,  $p = 0.10$ ).

The answers to the additional questions are shown in Appendix A.

## **Discussion**

IPR refers specifically to the legal rights resulting from intellectual activity in the industrial, scientific, literary and artistic fields [4]. In the context of healthcare, IP can result from novel devices or modifications improving already existing medical devices, including learning packages (software, data, written work), designs and images, and even new patient care procedures [5]. IP is a tool that can promote the movement of ideas from academia to industry and eventually to patients [1] [3]. A strong IPR provides numerous benefits to inventors (medical doctors, clinical and medtech researchers) in initiating or continuing R&D. For instance, patent owners (universities or hospitals) can acquire secondary funding from industries through patent out-licensing [3]. A good IPR also helps the research team to gain tertiary grants from governmental resources. An established IPR may further promote academia-industry R&D collaboration or generate university spin-off or start-up companies, leading to successful clinical implementation of new medical devices for the benefit of patients [3].

Historically, the significance of clinicians as "innovators" in the medical device industry has been well recognized. Bogers et al., in a survey of studies on innovation across industries, suggested two possible explanations relating to the significance of clinicians'

role in this field: they have specific knowledge of their unmet clinical needs and methods, which may be difficult to transfer. They are in a position to benefit from their own innovation [6] directly. Clinicians have thus inherently contributed to the invention of technologies underlying medical devices [2].

Here we have a critical paradox. Academic or clinical researchers with significant potential to contribute to medical device innovation often lack the fundamental knowledge and awareness relating to business mindset and in-depth knowledge of IP and IP-related issues. This deficit directly affects their ability to proceed efficiently with patenting their inventions [3]. Clinicians are unaware of the potential loss of IP protection resulting from an academic presentation or publication [1]. Furthermore, the lack of sufficient knowledge regarding what is considered a "public disclosure" of research findings may result in sabotaging the patentability of any invention arising from data contained in the publication. [3]. In addition, most clinicians working at teaching hospitals lack an understanding as to the definition of "employees' inventions" and how they may be affected by this. An "employees' invention," as defined by the Patent Act 1977, is an invention which, by its very nature, is within the scope of the business of the employer and was achieved by past or present duties of the employee [5]. Thus, many researchers unknowingly transfer their

valuable ideas to outside sources while their employers (universities or hospitals) remain out of the process. Considering all of these factors, the IP task force in the EAES technology committee decided to promote an IP awareness campaign. The current survey was the first step activity in organizing attractive and effective IP training programs for all EAES members.

As demonstrated in the results of the current survey, surgeons are by nature, full-time problem thinkers, focusing on dissatisfaction with current devices on various points: price, performance, usability, maintenance etc. The study has also revealed that surgeons are also problem solvers, continuously thinking of solutions for the problems identified. More than 66% of survey participants report reaching specific solutions by themselves. The authors believe that more solutions may have been continued to substantial R&D if their IPs had been correctly protected, subsequently gaining adequate funding. Unfortunately, nearly 60% of respondents disclosed their ideas and solutions inappropriately, via outside communications, including presenting at congresses and journal publications, without adequate IP protection beforehand. Simply speaking, this particular issue was mainly due to a lack of understanding of the notion of "employees' inventions," as well as a lack of understanding of the "public disclosure" principles. Lack of such basic IP knowledge might

result in a big loss of IPR for the original inventors (clinicians), for potential owners (universities and hospitals), and eventually for future beneficiaries (patients). Despite the dismaying amount of surgeons who inappropriately disclosed information, there were 29% of respondents who did not speak about their new ideas (Table 4). However, they reported that they kept silent mostly due to negative or passive reasons, not because they were careful enough about idea disclosure.

In this study, the authors viewed those who correctly recognized the existence/non-existence of institutional IP division as "responders with strong IP awareness," whereas those who did not as "responders with weak IP awareness." Although this group designation needs further validation, we observed several differences in behaviour patterns between the two. Most EAES members, regardless of IP awareness, felt frustrated with current medical devices. However, the number of members who took real actions, e.g. "purveying specific solutions" or "attracting industry's interest," was significantly higher in the strong IP awareness group. It was unfortunate that this "high conscious" group could not show better scores in "precautions prior to disclosure" and "careless disclosure." We have two possible explanations: First, as surgeons, we are eager to think up new ideas to solve clinical problems and are willing to share them with industries without taking

adequate measures to protect our IPR. Second, the cause and effect can potentially be reversed, as members who faced IP-related issues might have no choice but to improve their IP knowledge and skills on their own.

The reasons why we as clinicians do not have high IP awareness may be multifactorial. The lack of legal education, including basic IP training in the medical school curriculum, might be partially responsible. The lack of post-graduate, continuing education programs to teach the basic principles of IP and related issues can be another explanation. Most of all, the lack of motivation for IP protection among clinicians might, in fact, be the strongest factor, further hampered due to the tech transfer offices themselves. In some universities/hospitals, the tech transfer office, which deals with IPR issues, is often viewed as the entity that pushes the brakes on collaborations between clinician innovations and industry. As medical innovation and IP in the area of medical devices is relatively new, some tech transfer offices have failed to adapt their strategy regarding industry collaboration. As IPR is the most important factor in pharma innovation, tech transfer offices do not allow any IP acquisitions by industry. Medical device innovation has a much faster turnaround, requiring much less funding than pharma innovation. As such, tech transfer offices should adapt to promote clinician innovation by allowing the release of IPR



to the industry in return for royalties, for example. In future EAES IP training programs, clarification as to why we medical professionals should hold ourselves accountable for the protection and effective use of our IPs will be made.

There are several limitations to our study. First, the response rate of the survey was low, with only 4.8%. However, looking at this number from a different angle, this low collection rate might reflect low awareness or lack of interest regarding IP issues among clinicians. Second, there were several biases in the profession, gender and workplace. The nature of EAES as a "society of surgeons" might explain these biases. Further study, such as a comparison between clinicians and engineers, is necessary to determine the significance. Third, only a single format survey was distributed in this study, not taking into consideration the multi-nation nature of the EAES. Patent prosecution procedures, as well as legal understandings of inventorship and ownership, interpretation of "employees' inventions" may indeed vary by country. As such, further activities and campaigns are needed to inspire EAES members to learn more about IP and IP-related issues within their specific region or country.

## **Conclusions**

The current level of awareness relating to IP and IP-related issues is relatively low among EAES members. A structured IP training program to gain fundamental IP knowledge and skills should be considered a necessity for clinicians, preventing loss of legitimate rights and avoiding failure in the clinical implementation of innovative devices to benefit patients.

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## **Disclosures**

Drs. Nakajima, Mintz, Nickel, Arezzo and the remaining members of the EAES technology committee have no conflicts of interest or financial ties to disclose.

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## **Legends**

Fig 1	Survey outline
Table 1	Survey participants demographics
Table 2	Needs and idea related behaviour
Table 3	Precautions before idea disclosure
Table 4	Reasons why they did NOT speak their ideas
Table 5	Comparison of IP-related behaviours between strong IP awareness and weak IP awareness members
Appendix A	Do you have any similar experiences?