The EAES intellectual property 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 behaviors among 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, behaviors before and after idea disclosures.

Results One hundred and seventy-nine completed forms were obtained through an email campaign conducted twice in 2019 (response rate = 4.8%). There was a dominancy 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 percent 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

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 [1–3]. 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.

Members of the study Group “The EAES Technology Committee” were listed in Acknowledgements.

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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 behaviors among 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 Seville, 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 disclosure, and (7) any experience relating to patent application. The additional questions are listed in Appendix. All answers were compiled, and the numbers were tarried 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 3728 and 3719 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 dominancy in male (91%), medical doctors (99%) from European countries (79%). The age and clinical experience distribution suggested that most of the respondents 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 public forums.

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"
Fig. 1  Survey outline
(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

### Table 1 Survey participants demographics

| Category                        | Total number of participants |
|---------------------------------|-----------------------------|
| Total number of participants    | 179                         |
| Medical doctor\(^a\)            | 176                         |
| Gender                          |                             |
| Male                            | 162                         |
| Female                          | 17                          |
| Age, years                      |                             |
| \(< 30\)                        | 2                           |
| \(30–40\)                       | 59                          |
| \(40–50\)                       | 45                          |
| \(50–60\)                       | 47                          |
| \(> 60\)                        | 28                          |
| Place of work\(^b\)             |                             |
| University hospitals            | 89                          |
| Public general hospitals        | 51                          |
| Private teaching hospitals      | 18                          |
| Country                         |                             |
| Europe                          | 121                         |
| Asia                            | 29                          |
| United States                   | 4                           |
| Subspecialty\(^b\)              |                             |
| Gastrointestinal surgery        | 170                         |
| Endocrine surgery               | 22                          |
| Breast surgery                  | 10                          |
| Thoracic/pulmonary surgery      | 4                           |
| Clinical experience, years      |                             |
| \(< 5\)                         | 16                          |
| \(5–10\)                        | 41                          |
| \(10–20\)                       | 38                          |
| \(20–30\)                       | 45                          |
| \(> 30\)                        | 38                          |

\(^a\)Remaining 3 participants: 1 nurse, 1 engineer, 1 medical student

\(^b\)Multiple answers allowed

### Table 2 Needs and idea related behavior

| Description                                              | Yes | No |
|----------------------------------------------------------|-----|----|
| Frustration with current medical devices\(^a\)             | 130 | 49 |
| Price                                                    | 86  | 94 |
| Basic performance                                        | 58  | 42 |
| Optional performance                                     | 55  | 45 |
| Usability                                                | 52  | 48 |
| Malfunction                                              | 45  | 55 |
| Maintenance                                              | 37  | 63 |
| Device size                                              | 36  | 64 |
| Device weight                                            | 30  | 70 |
| After sales support                                      | 30  | 70 |
| Specific idea/solution for new devices                   | 84  | 16 |
| Disclosure of idea/solution\(^a\)                        | 60  | 40 |
| Spoke to IP division/office                              | 18  | 82 |
| Spoke to industry person                                 | 33  | 67 |
| Spoke to colleagues                                      | 32  | 68 |
| Spoke to mentors                                         | 23  | 77 |
| Presented at scientific sessions                         | 13  | 87 |
| Presented at invited talks                               | 7   | 93 |
| Published on journals                                    | 7   | 93 |

\(^a\)Multiple answers allowed

### Table 3 Precautions before idea disclosure

| Description                                       | Yes | No |
|---------------------------------------------------|-----|----|
| Consulted to institutional IP division             | 12  | 88 |
| Applied patent before Presentation/publication    | 11  | 89 |
| Concluded NDA with disclose                       | 9   | 91 |
| Consulted to colleague who had IP knowledge        | 5   | 95 |
| Consulted to outside supporting office             | 5   | 95 |
| No specific preparation                            | 36  | 64 |

60 responses, multiple answers allowed

### Table 4 Reasons why they did NOT speak about their ideas

| Description                                             | Yes | No |
|---------------------------------------------------------|-----|----|
| I was just too busy to take action                      | 13  | 87 |
| I thought my idea was not interesting enough            | 9   | 91 |
| I did not know the appropriate time and place           | 9   | 91 |
| I was afraid of too many troubles ahead                 | 5   | 95 |
| I was afraid of expenses                                | 3   | 97 |
| I was afraid people would make fun of it                | 3   | 97 |
| I was afraid someone would steal that idea              | 3   | 97 |
| I thought I was swerving from my duty                   | 2   | 98 |

25 responses, multiple answers allowed
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.

**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.
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.
Appendix

|                  | Tally |
|------------------|-------|
| I spoke about my idea to a company without an NDA | 8     |
| I spoke about my idea to a company, and they proceeded IP filing and product planning without any notice to me | 12    |
| I talked about my idea at a congress / seminar before filing a patent application | 16    |
| I spoke about my idea to an exhibitor at a congress exhibition booth | 8     |
| I did not take any action since I thought my idea was not worth it, but others filed the similar idea afterward | 11    |
| I spoke about my idea to a company asking them to apply for patent by themselves, since I thought patent application process was too troublesome | 25    |
| I had no idea whether my idea was valuable as IP | 3     |
| I worked on a project under supervision, and later found out that a patent was filed without my name on it | 36    |

84 responses, multiple answers allowed

Do you have any similar experiences?

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Declarations

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