Subjective Thoughts of the General Population on the Development, Management and Future use of Implantable Medical Devices

Márta Péntek*

Health Economics Research Center, University Research and Innovation Center, Doctoral School of Innovation Management, Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, pentek.marta@uni-obuda.hu

Anikó Vágvölgyi*

Parexel International, Hermina út 17, H-1146 Budapest, Hungary, aniko.vagvolgyi@parexel.com

Áron Hölgyesi

Health Economics Research Center, University Research and Innovation Center; Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, holgyesi.aron@uni-obuda.hu

Miklós Weszl

Department of Translational Medicine, Semmelweis University, Tűzoltó u. 37-47, H-1094 Budapest, Hungary, miklos.weszl@mdrpros.com

Levente Kovács

Physiological Controls Research Center, University Research and Innovation Center, Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, kovacs@uni-obuda.hu

Petra Baji

Musculoskeletal Research Unit, Bristol Medical School, University of Bristol, Level 1 Learning and Research Building Southmead Hospital, BS10 5NB, Bristol, United Kingdom, petra.baji@bristol.ac.uk

Zsombor Zrubka* and László Gulácsi*

Health Economics Research Center, University Research and Innovation Center, Doctoral School of Innovation Management, Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, zrubka.zsombor@uni-obuda.hu; gulacsi@uni-obuda.hu
**The two authors have contributed equally.*

Abstract: The successful functioning of implantable medical devices (IMDs) requires informed, engaged and compliant patients, who can recognize and act in case of malfunctions and cybersecurity problems. The aims of this study were to assess how informed the general population is about the authorization requirements, functioning and data management of IMDs. To assess participants involvement in the topic, current and subjectively expected use of IMDs at older ages were also explored. Altogether, 1400 respondents aged 40 years and over, representative for the Hungarian population (aged 40+) by main demographic characteristics, were involved in a cross-sectional online survey before the Medical Device Regulation (2017/745) has become applicable in May 2021. Most respondents were convinced that IMDs go under clinical trial investigation before market entry, their identification and registration is guaranteed, and digital devices' information security and protection against cyberattacks are solved. Most of the differences by sociodemographic subgroups were observed regarding cybersecurity while previous experience with cyberattacks was also deterministic. In general, an overestimation for having IMDs at future ages was observed. Subjective life expectancy has shaped these expectations. Results suggest that the MDR responds to a social demand but also point to gaps in patient information practices. Our findings can be used to develop management and targeted patient information strategies for new IMDs.

Keywords: implantable medical devices; development; management; awareness; subjective expectations; general population

1 Introduction

Technological and surgical advances over the past decades have made a wide range of medical devices available for implantation in humans. The first titanium dental implantation was performed in 1965, while today its prevalence is about

14% in the U.S. in age-group 65-74, with an increasing trend also among younger subjects [1] [2]. The first pacemaker insertion was in 1952, and today pacemaker is seen as a routine treatment in cardiology [3]. Surgical polypropylene meshes to repair the abdominal wall, introduced in the 1950s, have revolutionized the treatment of hernias [4]. The first intraocular lens was implanted in 1949, while currently this technology provides solution for the vision problem of millions of elderly people [5]. Hip arthroplasty has a longer history (the first attempts were done in 1891), however, current arthroplasty technologies' predecessor was developed in the 1960s [6]. Today, total hip replacement is one of the most frequent orthopaedic surgical procedures.

The spread of implanted devices has raised a series of new questions in patient care. Successful implantation is, indeed, a key moment but the survival and proper functioning of the implants depend on further factors. Unlike prescription medicines, patients living with implantable medical devices (IMDs) can skip medical checkups for years. The responsibility for identifying problems with an IMD that require medical attention lies largely with the patient. The patient may also have important role in operating the IMD that requires specific knowledge, engagement and compliance (e.g., blood glucose sensor linked to the mobile phone application). Moreover, digital IMDs that communicate with remote databases hold the risk of cyberattacks that need to be managed. Patients' role is highly relevant also in managing traditional (not AI-based) devices. For instance, the *"do's and don'ts"*, related to an implanted bone fixation (e.g., whether infrared saunas are allowed or not, what the early signs are of dislocations or infections) must be clear. Overall, patients' level of knowledge about the IMD can be decisive for the outcome of IMDs which elevates the importance of 'informed patient' concept in healthcare to a higher level.

This need has been addressed by the European Medical Device Regulation (MDR 2017/745, applicable since 26 May 2021) that put reinforced legal system for IMDs [7]. Manufacturers must supply the patient an 'implant card' and a series of information that include identification of the device, warnings, precautions, measures to be taken, expected lifetime of the device, necessary follow-ups and any additional information that is needed for the safe use of the device. This regulation is definitely an important step forward but does not guarantee that patients will embrace the information provided. Strategies need to be developed to make patient information and education efficient. This requires research that explores how (well) informed the population is about different aspects of the authorization process and management of IMDs that are relevant for the lay public (as potential future patients, IMD user patients or informal caregivers of patients with IMDs), identifies subgroups at risk and topics that require extra attention in patient education.

The extent to which patients are involved (directly or indirectly) with IMDs can determine how informed they are, and how open they are to novel information. Individuals' subjective expectations on having (or not) IMD in the future may

shape their interest in IMDs and thus their awareness, health-related decisions and health behavior. Subjective health expectations have gained attention in health economics research in the past decades. Brouwer and colleagues (year 2005) explored subjective health expectations of the general population in the Netherlands in terms of subjective life expectancy and health-related quality of life (HRQoL) at older ages [8]. They found that, in general, the adult population tends to underestimate their own future HRQoL by the age of 70 and over, while overestimate their life expectancy. Péntek and colleagues reported similar findings in population surveys in Hungary [9-11]. Research data suggest that the gap can be significant between objective (statistical) and subjective expectations both among the public and in specific patient populations [12] [13]. Unrealistic subjective expectations may cause unnecessary burden and lead to wrong health-related decisions. Subjective health expectations may also impact the valuation of different health states and thus the calculation of quality-adjusted life years (QALYs), a key element of health economic evaluations [14-17]. Despite the importance of the topic, no study has yet been done on people's subjective expectations, whether they will have, when and what type of IMDs in the future.

The objectives of this research were two-fold. First, we aimed to assess how knowledgeable the general population is about the authorization requirements and data management of IMDs. Second, we wanted to explore the subjective expectations of the public on having IMDs at older ages, considering their subjective life expectancy, while analyzing their sociodemographic subgroup characteristics.

2 Methods

2.1 Study Design and Participants

This study was part of a larger research project, details of which have been reported elsewhere [18] [19]. In brief, a cross-sectional online survey was performed (year 2021) in Hungary. Recruitment and data collection were conducted by a market survey company, respondents were invited via email from an online panel. Quota sampling was applied to achieve representativeness for the general Hungarian population aged 40 and over by age group, sex, educational level and residence. Inclusion criteria were as follows: age 40 years or older, provided informed consent to participate in the study. The study was approved by the Hungarian Medical Research Council (no. IV/5651-1/2021/EKU).

2.2 The Questionnaire

Respondents' sociodemographic characteristics were recorded. The research survey included three modules. The first focused on the epidemiology of IMDs, shared decision making about implantation and patients' self-reported awareness of their implants [18, 20-22]. The second investigated respondents' preferences towards artificial intelligence (AI)-based medical interventions [19] [23]. The third module is presented an analyzed in this current paper [24-26].

2.2.1 Knowledge on IMD Authorization and Management

The participants' knowledge, concerning the authorization and management of IMDs were approached with six questions, formulated by our study group. The questions were as follows:

1) Do you think implantable medical devices (implants) are always placed on the market after clinical trials as the drugs?' (Hereinafter: Clinical trial)
2) Do you think implantable medical devices (implants) have a unique identifier that allows the precise identification of each implant and the person wearing it?' (Hereinafter: Unique identifier)
3) Do you think after implantation, the person wearing the implant is entered in a patient register where his/her details are recorded?' (Hereinafter: Patient register)
4) Do you think that marketed implantable medical devices (implants) could include devices that communicate electronically to send data on the status of the patient and the implant to an authorized medical database?' (Hereinafter: Electronic database)
5) Do you think implantable electronic medical devices that electronically send data about the patient's status to an authorized medical database are subject to regulatory controls for information security and privacy?' (Hereinafter: Regulatory check)
6) Do you think it possible that an implanted electronic medical device could be subject to a cyberattack (e.g., malfunction caused by a computer virus, data theft by cybercriminals, extortion)?' (Hereinafter: Can be subject to cyberattack)

2.2.2 Subjective Expectations for Future Ages

Subjective expectations on having IMDs (hip replacement, knee replacement, cataract surgery (artificial lens in the eye), dental implant, pacemaker, coronary stent, abdominal surgical mesh, glucose sensor (continuous glucose sensor, CGS), other IMD, no IMD) at future ages were surveyed separately for ages 50, 60, 70, 80 and 90. (These age boundaries were used in previous subjective health

expectations studies and we found them reasonable for the investigation of IMD take up with ageing.) Results on pacemaker, CGM and dental implants have published elsewhere [26]. We report in this paper detailed analyses on the other IMDs.

Respondents' subjective life-expectancy was surveyed, and results were used for subgroup analyses of subjective expectations on IMDs. Those who did expect to be alive at the specific ages presented in the subjective expectations questions are called hereinafter as 'survivors' while those who expect to live shorter as 'non-survivors'.

2.3 Statistical Analyses

Data were recorded in an IBM SPSS Statistics 25 database. Regarding the questions on subjective expectations, only those respondents were considered in the analyses who were younger than the age in question. Descriptive statistics were performed. Subgroup comparisons of categorical variables were conducted using Chi square tests.

3 Results

3.1 Sample Characteristics

The mean age of the respondents (N=1400) was 58.4 (SD=11.1; minimum=40, maximum=85, median=58.0) years. Main sociodemographic characteristics of the total sample (that coincides with the group of participants younger than age 90, as the oldest respondent was 85 years old) and of subsamples younger than age 50, 60, 70 and 80 are presented in Table 1. Missing data was found only for the 'Paid work' question, these respondents were excluded only for the analyses of this variable.

Table 1
Sociodemographic characteristics of the respondents

Characteristics	**Respondents Age**				
	<50 years	***<60 years***	***<70 years***	***<80 years***	***<90 years (Total sample)***
N	378	739	1148	1369	1400
Sex					
female	202 (53.4%)	403 (54.5%)	644 (56.1%)	738 (53.9%)	752 (53.7%)
male	176 (46.6%)	336 (45.5%)	504 (43.9%)	631 (46.1%)	648 (46.3%)

Education					
primary	139 (36.8%)	259 (35.0%)	369 (32.1%)	405 (29.6%)	410 (29.3%)
secondary	133 (35.2%)	269 (36.4%)	448 (39.0%)	525 (38.3%)	533 (38.1%)
tertiary	106 (28.0%)	211 (28.6%)	331 (28.8%)	439 (32.1%)	457 (32.6%)
Residence					
capital	85 (22.5%)	154 (20.8%)	231 (20.1%)	302 (22.1%)	315 (22.5%)
city	190 (50.3%)	390 (52.8%)	624 (54.4%)	733 (53.5%)	749 (53.5%)
village	103 (27.2%)	195 (26.4%)	293 (25.5%)	334 (24.4%)	336 (24.0%)
Paid work*					
no	16 (4.2%)	30 (4.2%)	62 (5.5%)	82 (6.1%)	63 (6.1%)
yes	351 (92.9%)	369 (95.8%)	1062 (94.5%)	1257 (93.9%)	1287 (93.9%)
Married / having a partner					
no	143 (37.8%)	281 (38.0%)	434 (37.5%)	532 (38.9%)	546 (39.0%)
yes	235 (62.2%)	458 (62.0%)	714 (62.2%)	837 (61.1%)	854 (61.0%)

*Sample size for the 'Paid work' question in age groups younger than 50 / 60 / 70 / 80 / 90 years was 367 / 722 / 1124 / 1339 / 1370, respectively.

In subgroups aged younger than 50, 60, 70, 80 and 90, altogether 21.2%, 23.0%, 26.9%, 30.2% and 30.9% of the participants were living with at least one IMD at the time of the survey, respectively. Analysis by socioeconomic characteristics revealed significant differences only by the place of residence, and educational level in subgroups younger than age 80 and 90. (Table 2)

Table 2
Respondents living with or without IMD at the time of the survey by sociodemographic subgroups

Characteristics	**Respondents Age**									
	<50 years (N=378)		***<60 years (N=739)***		***<70 years (N=1148)***		***<80 years (N=1369)***		***<90 years (N=1400)***	
Has IMD	***Y***	***N***	***Y***	***N***	***Y***	***N***	***Y***	***N***	***Y***	***N***
N	80	298	170	569	309	839	413	956	433	967
Sex	p=0.658		p=0.239		p=0.210		p=0.209		p=0.145	
female	41 51.3%	161 54.0%	86 50.6%	317 55.7%	164 53.1%	480 57.2%	212 51.3%	526 55.0%	220 50.8%	532 55.0%
male	39 48.8%	137 46.0%	84 49.4%	252 44.3%	145 46.9%	359 42.8%	201 48.7%	430 45.0%	213 49.2%	435 45.0%
Education	p=0.075		p=0.092		p=0.118		**p=0.001**		**p=0.000**	
primary	21 26.3%	118 39.6%	48 28.2%	211 37.1%	91 29.4%	278 33.1%	103 24.9%	302 31.6%	104 24.0%	306 31.6%
secondary	31 38.8%	102 34.2%	66 38.8%	203 35.7%	115 37.2%	333 39.7%	148 35.8%	377 39.4%	153 35.3%	380 39.3%
tertiary	28 35.0%	78 26.6%	56 32.9%	155 27.2%	103 33.3%	228 27.2%	162 39.2%	277 29.0%	176 40.6%	281 29.1%

Residence	**p=0.046**		**p=0.041**		**p=0.028**		**p=0.004**		**p=0.002**	
capital	25 31.3%	60 20.1%	47 27.6%	107 18.8%	73 23.6%	158 18.8%	110 26.6%	192 20.1%	117 27.0%	198 20.5%
city	40 50.0%	150 50.3%	84 49.4%	306 53.8%	173 56.0%	451 53.8%	222 53.8%	511 53.5%	234 54.0%	515 53.3%
village	15 18.8%	88 29.5%	39 22.9%	156 27.4%	63 20.4%	230 27.4%	81 19.6%	253 26.5%	82 18.9%	254 26.3%
Paid work*	p=0.686		p=0.611		p=0.201		p=0.071		p=0.073	
no	4 5.2%	12 4.1%	8 4.8%	22 3.9%	21 7.0%	41 5.0%	32 7.9%	50 5.3%	33 7.8%	50 5.3%
yes	73 94.8%	278 95.9%	157 95.2%	535 96.1%	281 93.0%	781 95.0%	372 92.1%	885 94.7%	391 92.2%	896 94.7%
Married / having a partner	p=0.743		p=0.634		p=0.566		p=0.365		p=0.467	
no	29 36.3%	114 38.3%	62 36.5%	219 38.5%	121 39.2%	313 37.3%	168 40.7%	364 38.1%	175 40.4%	371 38.4%
yes	51 63.8%	184 61.7%	108 63.5%	350 61.5%	188 60.8%	526 62.7%	245 59.3%	592 61.9%	258 59.6%	596 61.6%

IMD=implantable medical device; Y=yes; N=no; Sample size for the 'Paid work' question in age groups younger than 50 / 60 / 70 / 80 / 90 years was 367 / 722 / 1124 / 1339 / 1370, respectively.

3.2 Knowledge about the Marketing Authorization and Data Management of IMDs

The distribution of participants' responses related to the authorization, management and security of the IMDs are presented in Figure 1. Most of the respondents (84.7%) thought that IMDs are tested in clinical trials such as the drugs before their marketing authorization, and users' (patient) details are recorded in a registry (84.6%). The prevailing opinion among the majority of participants (80.0%) was that it is necessary for the IMDs to have a unique identifier. A slightly lower number of respondents (72.7%) thought that IMDs could send data electronically on the status of the patient and the implant to an authorized medical database, and that this data transfer is subject to regulatory controls (71.8%). Related to the question if an IMD could be a subject to a cyberattack, just over half of the respondents (56.2%) perceived this was a realistic threat.

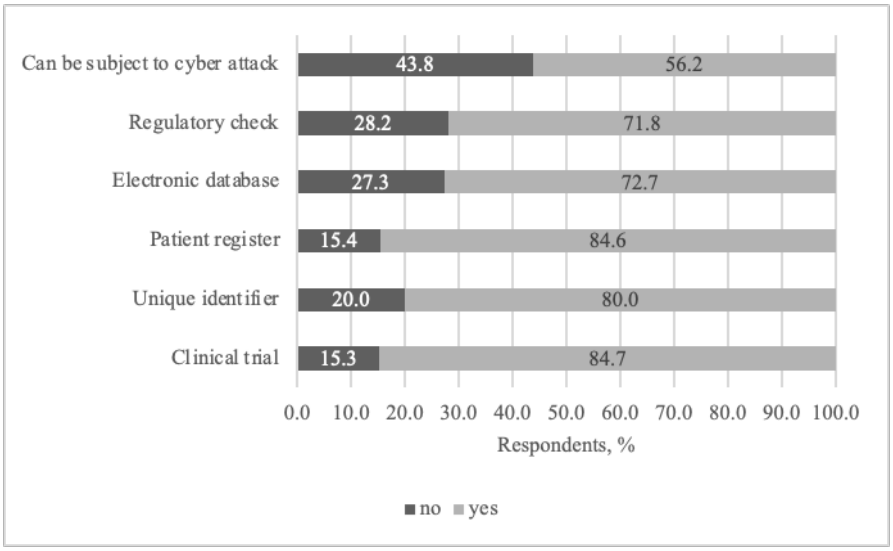


Figure 1
Distribution of participants' responses regarding the authorization and data management of implantable medical devices

Respondents' ideas about the process of market entry and follow-up of IMDs by sociodemographic subgroups are presented in Table 3.

The disparity in responses by age group and by education was found to be statistically significant for four out of the six questions (by age group: Clinical trial, Unique identifier, Patient register and Cyberattack questions; by education: Clinical trial, Unique identifier, Electronic database and Cyberattack questions). Analyzing the responses by being married or having a partner shows significant difference in the distribution for three questions (Clinical trial, Unique identifier and Patient register questions), however the difference by sex was only significant for 2 questions (Electronic database and Cyberattack questions). The place of residence had significant impact ($p=0.001$) on the answers for 1 question, related to Cyberattacks, while stratification by having a paid work shows no impact on the distribution of the answers. All in all, the Cyberattack question showed the most significant differences in this sociodemographic subgroup analysis. (Table 3)

Table 3

Comparison of respondents' thoughts on the authorization and data management of IMDs by sociodemographic subgroups

	Clinical trial		**Unique identifier**		**Patient register**		**Electronic database**		**Regulatory check**		**Can be subject to a cyberattack**	
	Y	***N***	***Y***	***N***	***Y***	***N***	***Y***	***N***	***Y***	***N***	***Y***	***N***
Age group, years	**p=0.000**		**p=0.000**		**p=0.000**		p=0.419		p=0.796		**p=0.046**	
40	29 78.4%	8 21.6%	23 62.2%	14 37.8%	25 67.6%	12 32.4%	24 64.9%	13 35.1%	24 64.9%	13 35.1%	13 35.1%	24 64.9%
41-50	284 77.4%	83 22.6%	275 74.9%	92 25.1%	304 82.8%	63 17.2%	264 71.9%	103 28.1%	256 69.8%	111 30.2%	210 57.2%	157 42.8%
51-60	317 84.8%	57 15.2%	317 84.8%	57 15.2%	326 87.2%	48 12.8%	280 74.9%	94 25.1%	273 73.0%	101 27.0%	206 55.1%	168 44.9%
61-70	360 89.3%	43 10.7%	334 82.9%	69 17.1%	357 88.6%	46 11.4%	289 71.7%	114 28.3%	292 72.5%	111 27.5%	228 56.6%	175 43.4%
71-80	176 89.3%	21 10.7%	157 79.7%	40 20.3%	160 81.2%	37 18.8%	148 75.1%	49 24.9%	143 72.6%	54 27.4%	121 61.4%	76 38.6%
81-90	20 90.9%	2 9.1%	14 63.6%	8 36.4%	13 59.1%	9 40.9%	13 59.1%	9 40.9%	17 77.3%	5 22.7%	9 40.9%	13 59.1%
Sex	p=0.236		p=0.851		p=0.415		**p=0.043**		p=0.889		**p=0.005**	
female	645 85.5%	107 14.2%	603 80.2%	149 19.8%	642 85.4%	110 14.6%	530 70.5%	222 29.5%	541 71.9%	211 28.1%	397 52.8%	355 47.2%
male	541 83.5%	107 16.5%	517 79.8%	131 20.2%	543 83.8%	105 16.2%	488 75.3%	160 24.7%	464 71.6%	184 28.4%	390 60.2%	258 39.8%
Education	**p=0.000**		**p=0.034**		p=0.073		**p=0.001**		p=0.139		**p=0.004**	
primary	315 76.8%	95 23.2%	311 75.9%	99 24.1%	334 81.5%	76 18.5%	272 66.3%	138 33.7%	281 68.5%	129 31.5%	204 49.8%	206 50.2%
secondary	467 87.6%	66 12.4%	431 80.9%	102 19.1%	463 86.9%	70 13.1%	391 73.4%	142 26.6%	383 71.9%	150 28.1%	306 57.4%	227 42.6%
tertiary	404 88.4%	53 11.6%	378 82.7%	79 17.3%	388 84.9%	69 15.1%	355 77.7%	102 22.3%	341 74.6%	116 25.4%	277 60.6%	180 39.4%

Residence	p=0.089		p=0.432		p=0.060		p=0.072		p=0.116		**p=0.012**	
capital	270 85.7%	45 14.3%	245 77.8%	70 22.2%	263 83.5%	52 16.5%	233 74.0%	82 26.0%	219 69.5%	96 30.5%	196 62.2%	119 37.8%
city	644 86.0%	105 14.0%	608 81.2%	141 18.8%	649 86.6%	100 13.4%	557 74.4%	192 25.6%	555 74.1%	194 25.9%	421 56.2%	328 43.8%
village	272 81.0%	64 19.0%	267 79.5%	69 20.5%	273 81.3%	63 18.8%	228 67.9%	108 32.1%	231 68.8%	105 31.3%	170 50.6%	166 49.4%
Paid work*	p=0.159		p=0.221		p=0.879		p=0.260		p=0.727		p=0.227	
no	66 79.5%	17 20.5%	71 85.5%	12 14.5%	71 85.5%	12 14.5%	65 78.3%	18 21.7%	61 73.5%	22 26.5%	52 62.7%	31 37.3%
yes	1097 85.2%	190 14.8%	1030 80%	257 20.0%	1093 84.9%	194 15.1%	935 72.6%	352 27.4%	923 71.7%	364 28.3%	719 55.9%	568 44.1%
Married / having a partner	**p=0.001**		**p=0.043**		**p=0.002**		p=0.109		p=0.115		p=0.120	
no	440 80.6%	106 19.4%	422 77.3%	124 22.7%	442 81.0%	104 19.0%	384 70.3%	162 29.7%	379 69.4%	167 30.6%	321 58.8%	225 41.2%
yes	746 87.4%	108 12.6%	698 81.7%	156 18.3%	743 87.0%	111 13.0%	634 74.2%	220 25.8%	626 73.3%	228 26.7%	466 54.6%	388 45.4%

*The number of respondents for the ‘Paid work’ question was N=1370.

Altogether 508 (36.3%) respondents have already experienced any cyberattack in their life, while 892 (63.7%) respondents have not. Among the cyberattack experienced participants, 375 (78.3%) indicated that it is possible that an implanted electronic medical device could be subject to a cyberattack (e.g., malfunction caused by a computer virus, data theft by cybercriminals, extortion), while in the non-experienced subgroup only less than half of the respondents (N=412, 46.2%) thought the same, the difference between the two subgroups was statistically significant ($p<0.001$). Comparing subgroups having or not IMD at the time of the survey revealed significant difference only for the patient register question. Among the respondents living with IMD 344 (79.4%) thought that after implantation the person wearing the implant is entered in a patient register where his/her details are recorded. In contrast, this share was 841 (87.0%) in the subgroup living without IMD ($p=0.000$). (Data not shown, but available on request.)

3.3 Subjective Expectations regarding IMDs for Future Ages

Respondents' estimations on having IMD(s) at older ages are presented in Table 4. In case of hip replacement and intraocular lens, the share of respondents who expect to have these IMDs increases with age up to age 80. Knee replacement, coronary stent and abdominal mesh increase up to age 70 and slightly decrease to age 80. However, a sharp decrease can be observed between age 80 and 90 in case of all the five IMDs. (Table 4)

Table 4
Subjective expectations on having IMDs at future ages

IMD	Subjectively expects to have…				
	at age 50 (N=378)	***at age 60 (N=739)***	***at age 70 (N=1148)***	***at age 80 (N=1369)***	***at age 90 (N=1400)***
Hip replacement	20 (5.3%)	50 (6.8%)	135 (11.8%)	161 (11.8%)	77 (5.5%)
Knee replacement	34 (9.0%)	86 (11.6%)	167 (14.5%)	167 (12.2%)	74 (5.3%)
Intraocular lens	28 (7.4%)	55 (7.4%)	168 (14.6%)	216 (15.8%)	111 (7.9%)
Coronary stent	12 (3.2%)	49 (6.6%)	82 (7.1%)	86 (6.3%)	52 (3.7%)
Abdominal mesh	9 (2.4%)	30 (4.1%)	62 (5.4%)	60 (4.4%)	24 (1.7%)
Other IMD	9 (2.4%)	23 (3.1%)	35 (3.0%)	30 (2.2%)	22 (1.6%)
None	202 (53.4%)	370 (50.1%)	474 (41.3%)	503 (36.7%)	554 (39.8%)

In the same sample, detailed data on the share of respondents living with IMDs have been published by Hölgyesi and colleagues [18]. We present subjective expectations on having IMDs in comparison with the actual prevalence of IMDs in the respective age groups in Figure 2. Overestimation of having IMDs at future

ages were observed for all IMDs (calculated as the percentage of respondents who expected to have IMD at a specific age minus the percentage of respondents who actually has IMD at that age), except for having hip replacement (-8.1%), intraocular lens (19.3%), coronary stent (-5.4%) or abdominal mesh (-2,8%) at age 90, and intraocular lens (-11.1%) or abdominal mesh (-0,2%) at age 80. The highest share of overestimation was observed for knee replacement at age 50, 60, 70 and 80 years of age (with a difference of 8.2%, 10.6%, 12.3% and 10.7%, respectively), but also hip replacement was substantially overestimated for age 70 and 80 (difference was 7.8% and 7.7%, respectively).

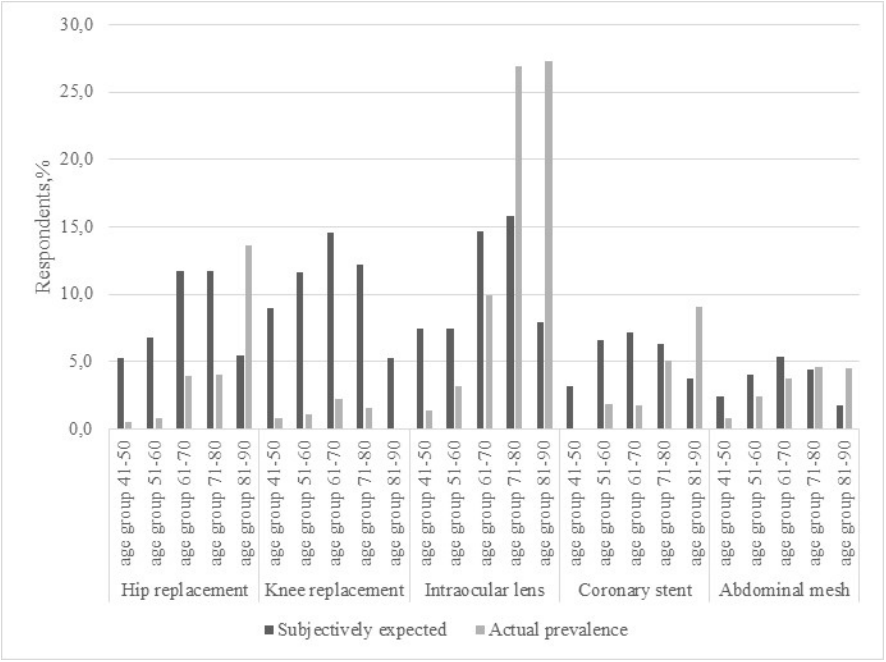


Figure 2
Subjective expectations of respondents having IMDs at future ages in comparison with the actual prevalence of IMDs in respective age groups

3.4 Analysis of Subjective Expectations on having IMDs at Older Ages by Subjective Life Expectancy

The average subjective life expectancy was 83.0 (SD=12.7, minimum=43, maximum=120, median=80.0) years in the sample. The share of respondents who expected to live up to age 50, 60, 70, 80 and 90 was 98.7%, 96.6%, 88.6%, 65.1% and 31.2%, respectively. (Figure 3) Overall, a drop in believing to survive up to age 90 can be observed in the sample.

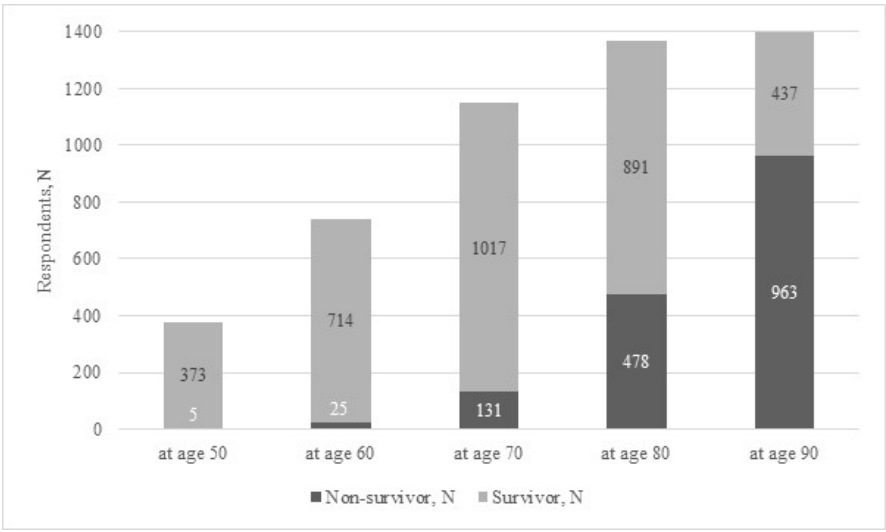
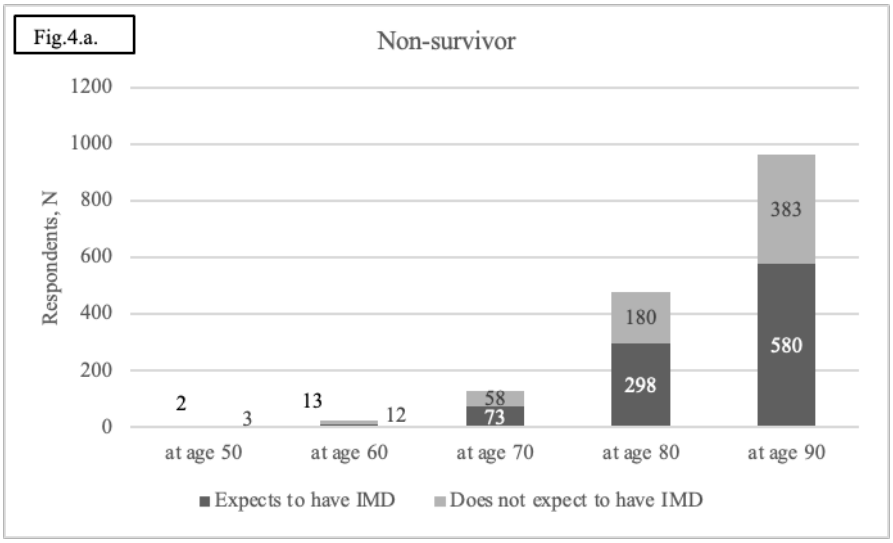


Figure 3
Respondents with shorter ('non-survivor') and equal or longer ('survivor') subjective life expectancy than ages 50, 60, 70, 80 and 90

We have analyzed subjective expectations on having IMD at older ages in relation to subjective life expectancy. In the 'non-survivor' subgroup, the sample was very small for ages 50 and 60 (N=5 and N=25, respectively), hence we did not do further analyses. However, for ages 70, 80 and 90, most of the 'non-survivors' expected to have IMD (55.7%, 62.3% and 60.2%, respectively). (Figure 4a) This means that they do not believe to live so long, but if they do, the majority expects to live with IMD. In the 'survivor' subgroup, the share of respondents expecting to have IMD at ages 50 and 60 was 46.6% and 49.9%, respectively, but for ages 70, 80 and 90 the majority expected to have IMD (59.1%, 63.7%, and 60.2%). (Figure 4b) Overall, the share of subjective expectations on having IMD at ages 70, 80 and 90 were very similar in the 'non-survivor' and 'survivor' subgroups.



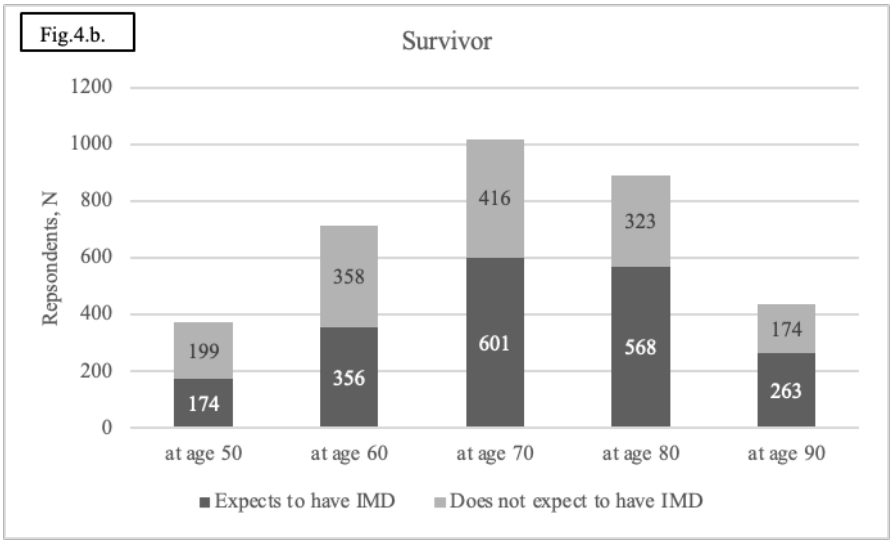


Figure 4
Subjective expectations on having IMD at older ages among subgroups with shorter (‘non-survivor’) and equal or longer (‘survivor’) subjective life expectancy than the age in question

4 Discussion

Study findings of this cross-sectional online survey suggest that the general public (with some subgroup differences) have had high trust in the authorization process and management of IMDs even before the application of the MDR 2017/745, including their clinical trial investigation before market entry, identification, registration, information security and protection against cyberattacks. Age and educational level seem to be important determinants, concerns regarding cybersecurity of IMDs are also driven by own cyberattack experiences. In terms of respondents' subjective expectations for their personal future as IMD users, an overestimation tendency of having IMDs at older ages (with some variations across different IMDs and exceptions in the oldest age group) was found.

The major strength of our research is that the survey was conducted right before the MDR 2017/745 became applicable, in May of 2021, in the EU. Hence the study reflects public beliefs that were formed before the introduction of this stricter and more detailed regulation. In this context, respondents' high level of trust in a high-quality authorization process and data management of IMDs deserves further consideration. Regulatory agencies worldwide mandate that IMDs undergo a rigorous evaluation process prior to their introduction in the market to verify safety and effectiveness. The exact requirements can vary depending on factors such as the device's classification, intended use and the regulatory environment of the country or region where it's being marketed. The medical devices are classified into different classes based on their potential risk associated with use. The Food and Drug Administration (FDA) in the USA and now the MDR, in the European Union (EU) align in classifying IMDs as high-risk, generally necessitating clinical trials before market approval [7] [27]. However, before the MDR was introduced, clinical trial was not mandatory for all IMDs. In fact, certain IMDs with simple design may still be exempt from clinical trials. In contrast, 84.7% of the participants surveyed thought that clinical trials were always required to verify safety and efficacy. Older age and higher educational levels seem to be important determinants of the positive answers.

Identification and data management of IMDs are crucial points in the MDR. We have found that 80.0% of the respondents believed that all IMDs have a unique identifier, 84.6% thought that the patients' and their IMD's data are recorded in registers, and 72.7% stated that the marketed IMDs could include devices that communicate electronically to send data on the status of the patient and the implant to an authorized medical database. These responses are in line with the current regulations but not that much with the former practice. Both the FDA and the EU MDR require Unique Device Identifier (UDI), for implantable medical devices [7] [28]. The UDIs aim to improve patient safety, enhance post-market monitoring, facilitate device traceability and allows easier recall if required. The sociodemographic subgroup analysis showed significant differences by age group, by education and by being married or having a partner.

The question of if an IMD could be subject to a cyberattack, has generated significantly dissimilar responses in most sociodemographic subgroups. The perception of the possibility for a cyberattack for IMDs was significantly lower for male participants. The analysis also correlated with age, education and place of residence, however, not in a linear way. In total, 56.2% of the respondents thought cyberattacks are a realistic threat, representing patients' confidence in the technology varies across different levels. Compared to previous studies, Fraiche and colleagues reported that only a few respondents described concerns around cybersecurity [29]. The findings reflect a rather optimistic perspective among nearly the half of the respondents. Even though, currently, there have been no documented cyberattacks targeting implanted pacemakers, defibrillators or other IMDs, the potential for cyberattacks on these medical devices is a rapidly increasing concern that should be taken seriously [30-32]. Studies on cybersecurity in IMDs have uncovered vulnerabilities of various degrees of severity depending on the device [33]. Specifically, cardiac implants and implantable insulin pumps have been found to be susceptible to manipulation, potentially posing life-threatening security risks [34] [35]. Our results, with a varying levels of patients' trust, points out the need for the inclusion of cybersecurity issues, within informed consent [36]. Introducing cybersecurity into the fundamentals of patient care (from including cybersecurity competencies in early schooling to targeted patient cybersecurity education) a crucial practice that must be integrated into the healthcare system for a realistic awareness on the risks associated with carrying an IMD [37] [38].

Most participants (with some exceptions of certain age groups and IMDs) overestimated having IMDs at older ages. The gap between the subjective projections and current prevalence data can be driven by different factors. For instance, the prevalence of IMDs will most probably increase in the future with the development of new advanced IMDs, sensors, AI- and robot-assisted surgical methods and complex cyber-medical systems [39] [40]. This aspect can be especially relevant in younger age groups, who were asked to make estimations for four or five decades ahead (e.g., participants of age 40-50 estimated for ages 80 and 90). Also, previous studies revealed that most people underestimate their future health status (i.e., project to have more health problems than the respective age groups have) and thus think they will need IMDs at older ages. They may think also that access to IMDs will be easier due the increase in the number of suppliers and cost reductions with time. It would be worthwhile to explore respondents' motivations in more depth through qualitative research.

Our study has supported the deterministic role of subjective life expectancy (whether the respondent believes to live to old ages) on subjective expectations of having IMDs in the future. This is in line with previous findings on the role of subjective life expectancy in the subjective health-related quality of life expectations of the individuals [9]. Therefore, it is recommended to include a

subjective life expectancy question, in future studies, aiming to analyze in depth subjective expectations on IMDs.

Some boundaries of our study need to be noted. The sample was limited to age 40 and over, thus, the study does not provide information about the thoughts of younger age groups. IMDs was surveyed as a homogeneous group in the knowledge questions, even though respondents do not necessarily think the same about an issue for different IMDs. Due to feasibility reasons not all IMDs were included in the questionnaire (e.g., brain electrodes for Parkinsonism) but participants were allowed to report additional IMDs in free text. We relied on participants' self-report on IMDs they had, as the online design did not allow medical confirmation and further specifications. We did not focus on stakeholder groups (e.g., IMD developers, physicians, specific patient groups, experts responsible for supervising the IMD market) but on the public in general. Subjective expectations regarding living with IMDs were surveyed in 10-year age boundaries and not in a continuous life scale that could have provided more detailed data on the subjectively provisioned timing of IMD implantation. In subgroup analyses the number of participants was below five that increases the probability of type II error. We limited the analyses to descriptive statistics to provide a basic picture of the main data and multivariate analyses could refine the results.

These limitations deserve further exploration in future studies. It would be worthwhile also to assess how the implementation of MDR in everyday practice have changed patients' thoughts. Overall, we believe that this first explorative study provides a valuable basis for further investigations and has the potential to strengthen collaborations between IMD developers, clinicians, users, distributors, product managers and other relevant stakeholders.

Conclusions

The general public's perceptions on the authorization and data management of IMDs, reflect a greater control and higher level of regulation than what the reality was, prior to the introduction of MDR 2017/745, in the EU. In this sense, our study suggests that the new legislation responds to a social demand, but also points to gaps in patient information practices. It would be worth exploring how patients' thoughts on IMDs have changed, since the implementation of MDR. High levels of subjective expectations on having IMDs at older ages, indicate an interest and openness of society, towards advanced implantable medical technologies and underlines the importance of IMD development and research.

Our results can be used in the design management strategies for innovative IMDs. Subgroup differences (by sociodemographic characteristics and personal previous experiences) identified, can support the planning of more personalized and effective patient information and education policies.

Acknowledgements

The questionnaire survey, the data from which was used in this study, was supported by the Higher Education Institutional Excellence Program of the Ministry of Innovation and Technology in the framework of the 'Financial and Public Services' research project (TKP2020-NKA-02) at Corvinus University of Budapest. This project has been supported by the National Research, Development, and Innovation Fund of Hungary, financed under the TKP2021-NKTA-36 funding scheme 'Development and evaluation of innovative digital medical devices' at Obuda University.

Disclosure

Anikó Vágvölgyi worked in the project as PhD candidate (individual PhD program) at Obuda University. Parexel International did not provide funding for the research nor had any influence on it, and the contents expressed in the paper do not represent the company's views.

References

[1] Y. Smith. "History of dental implants." https://www.news-medical.net/health/History-of-Dental-Implants.aspx (accessed January 25, 2025)

[2] H. W. Elani, J. R. Starr, J. D. Da Silva, and G. O. Gallucci, "Trends in Dental Implant Use in the U.S., 1999-2016, and Projections to 2026," *J Dent Res,* Vol. 97, No. 13, pp. 1424-1430, Dec 2018, doi: 10.1177/0022034518792567

[3] N. M. van Hemel and E. E. van der Wall, "8 October 1958, D Day for the implantable pacemaker," *Neth Heart J,* Vol. 16, No. Suppl 1, pp. S3-4, Oct 2008 [Online] Available: https://www.ncbi.nlm.nih.gov/pubmed/18958267

[4] K. Baylon, P. Rodriguez-Camarillo, A. Elias-Zuniga, J. A. Diaz-Elizondo, R. Gilkerson, and K. Lozano, "Past, Present and Future of Surgical Meshes: A Review," *Membranes (Basel),* Vol. 7, No. 3, Aug 22 2017, doi: 10.3390/membranes7030047

[5] G. Davis, "The Evolution of Cataract Surgery," *Mo Med,* Vol. 113, No. 1, pp. 58-62, Jan-Feb 2016 [Online] Available: https://www.ncbi.nlm.nih.gov/pubmed/27039493

[6] S. R. Knight, R. Aujla, and S. P. Biswas, "Total Hip Arthroplasty - over 100 years of operative history," *Orthop Rev (Pavia),* Vol. 3, No. 2, p. e16, Sep 6 2011, doi: 10.4081/or.2011.e16

[7] E. Union. https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng (accessed January 25, 2025)

[8] W. B. Brouwer and N. J. van Exel, "Expectations regarding length and health related quality of life: some empirical findings," *Soc Sci Med,* Vol. 61, No. 5, pp. 1083-94, Sep 2005, doi: 10.1016/j.socscimed.2005.01.008

[9] M. Pentek *et al.*, "Subjective expectations regarding length and health-related quality of life in Hungary: results from an empirical investigation," *Health Expect,* Vol. 17, No. 5, pp. 696-709, Oct 2014, doi: 10.1111/j.1369-7625.2012.00797.x

[10] M. Pentek *et al.*, "Subjective expectations regarding ageing: a cross-sectional online population survey in Hungary," *Eur J Health Econ,* Vol. 20, No. Suppl 1, pp. 17-30, Jun 2019, doi: 10.1007/s10198-019-01059-w

[11] Z. Zrubka, A. Kincses, L. Gulacsi, L. Kovacs, and M. Pentek, "[Subjective expectations concerning life expectancy and age-related health burden]," *Orv Hetil,* Vol. 162, No. 23, pp. 911-923, Jun 6 2021, doi: 10.1556/650.2021.32124, Az elettartammal es az idoskori betegsegteherrel kapcsolatos szubjektiv varakozasok

[12] M. Pentek *et al.*, "Subjective health expectations of patients with age-related macular degeneration treated with antiVEGF drugs," *BMC Geriatr,* Vol. 17, No. 1, p. 233, Oct 10 2017, doi: 10.1186/s12877-017-0619-9

[13] M. Pentek, L. Gulacsi, B. Rojkovich, V. Brodszky, J. van Exel, and W. B. Brouwer, "Subjective health expectations at biological therapy initiation: a survey of rheumatoid arthritis patients and rheumatologists," *Eur J Health Econ,* Vol. 15 Suppl 1, pp. S83-92, May 2014, doi: 10.1007/s10198-014-0597-1

[14] F. E. van Nooten, X. Koolman, and W. B. Brouwer, "The influence of subjective life expectancy on health state valuations using a 10 year TTO," *Health Econ,* Vol. 18, No. 5, pp. 549-58, May 2009, doi: 10.1002/hec.1385

[15] F. E. van Nooten, N. J. van Exel, D. Eriksson, and W. B. Brouwer, ""Back to the future": Influence of beliefs regarding the future on TTO answers," *Health Qual Life Outcomes,* Vol. 14, p. 4, Jan 12 2016, doi: 10.1186/s12955-015-0402-6

[16] D. R. Rappange, W. B. Brouwer, and J. van Exel, "A long life in good health: subjective expectations regarding length and future health-related quality of life," *Eur J Health Econ,* Vol. 17, No. 5, pp. 577-89, Jun 2016, doi: 10.1007/s10198-015-0701-1

[17] S. A. Lipman, W. B. F. Brouwer, and A. E. Attema, "Living up to expectations: Experimental tests of subjective life expectancy as reference point in time trade-off and standard gamble," *J Health Econ,* Vol. 71, p. 102318, May 2020, doi: 10.1016/j.jhealeco.2020.102318

[18] A. Holgyesi *et al.*, "Epidemiology and patients' self-reported knowledge of implantable medical devices: Results of a cross-sectional survey in

Hungary," *PLoS One,* Vol. 18, No. 4, p. e0284577, 2023, doi: 10.1371/journal.pone.0284577

[19] A. Holgyesi *et al.*, "Robot-assisted surgery and artificial intelligence-based tumour diagnostics: social preferences with a representative cross-sectional survey," *BMC Med Inform Decis Mak,* Vol. 24, No. 1, p. 87, Mar 27 2024, doi: 10.1186/s12911-024-02470-x

[20] Á. Hölgyesi *et al.*, "MT31 Epidemiology and Patients' Knowledge of Implantable Medical Device Management and Safe Use: Results of a CROSS-Sectional Survey Among the General Population in Hungary," *Value in Health,* Vol. 25, No. 7, p. S538, 2022, doi: 10.1016/j.jval.2022.04.1310

[21] Á. Hölgyesi *et al.*, "MT21 Living With Orthopaedic Implants: Results of an Online Cross-Sectional Study in Hungary," *Value in Health,* Vol. 25, No. 12, pp. S381-S382, 2022, doi: 10.1016/j.jval.2022.09.1895

[22] M. Péntek *et al.*, "MT7 Patients' Experiences with Shared Decision Making about Implantable Medical Device Surgery: Results of a Cross-Sectional Survey in Hungary," *Value in Health,* Vol. 25, No. 7, p. S533, 2022, doi: 10.1016/j.jval.2022.04.1286

[23] Á. Hölgyesi *et al.*, "PCR258 Citizens' Preferences for Robot-Assisted Hip Replacement: Results of an Online Cross-Sectional Study in Hungary," *Value in Health,* Vol. 25, No. 12, p. S440, 2022, doi: 10.1016/j.jval.2022.09.2191

[24] M. Péntek *et al.*, "MT26 Citizens' Thoughts about Implantable Medical Devices: Results of a Cross-Sectional Survey Among the General Population in Hungary," *Value in Health,* Vol. 25, No. 7, p. S537, 2022, doi: 10.1016/j.jval.2022.04.1305

[25] M. Pentek, H. Á, Z. Zrubka, L. Kovács, and L. Gulácsi, "PCR58 Subjective Expectations on Having Implanted Medical Devices at Older Ages: Results of a Cross-Sectional Population Survey," *Value in Health,* Vol. 27, No. 6, p. S306, 2024, doi: 10.1016/j.jval.2024.03.1937

[26] M. Péntek *et al.*, "Subjective Expectations on Living with Innovative Digital Implantable Medical Devices at Older Ages," in *2024 IEEE 28th International Conference on Intelligent Engineering Systems (INES)*, 17-19 July 2024 2024, pp. 000043-000048, doi: 10.1109/INES63318.2024.10629145

[27] FDA. "Device advice: Comprehensive regulatory assistance." https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance (accessed January 25, 2025)

[28] FDA. "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices."

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices (accessed January 25, 2025)

[29] A. M. Fraiche, D. D. Matlock, W. Gabriel, F. A. Rapley, and D. B. Kramer, "Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators," *Am J Cardiol,* Vol. 149, pp. 42-46, Jun 15 2021, doi: 10.1016/j.amjcard.2021.03.023

[30] M. Chauvin, O. Piot, S. Boveda, L. Fauchier, and P. Defaye, "Pacemakers and implantable cardiac defibrillators: Must we fear hackers? Cybersecurity of implantable electronic devices," *Arch Cardiovasc Dis,* Vol. 116, No. 2, pp. 51-53, Feb 2023, doi: 10.1016/j.acvd.2022.12.002

[31] V. Rajasekar, P. Jayapaul, S. Krishnamoorthi, and M. Saračević, "Secure Remote User Authentication Scheme on Health Care, IoT and Cloud Applications: A Multilayer Systematic Survey," *Acta Polytechnica Hungarica,* Vol. 18, No. 3, pp. 87-106, 2021, doi: 10.12700/APH.18.3.2021.3.5

[32] M. Čergeť and J. Hudec, "Cyber-Security Threats Origins and their Analysis," *Acta Polytechnica Hungarica,* Vol. 20, No. 9, pp. 23-41, 2023, doi: 10.12700/APH.20.9.2023.9.2

[33] L. Pycroft and T. Z. Aziz, "Security of implantable medical devices with wireless connections: The dangers of cyber-attacks," *Expert Rev Med Devices,* Vol. 15, No. 6, pp. 403-406, Jun 2018, doi: 10.1080/17434440.2018.1483235

[34] B. Patel and A. N. Makaryus, "Cardiac implantable electronic devices and cybersecurity," *Expert Rev Med Devices,* Vol. 18, No. sup1, pp. 69-77, Dec 2021, doi: 10.1080/17434440.2021.2007075

[35] C. Li, A. Raghunathan, and N. K. Jha, "Hijacking an insulin pump: Security attacks and defenses for a diabetes therapy system," presented at the 2011 IEEE 13th International Conference on e-Health Networking, Applications and Services, Columbia, MO, USA, 2011

[36] L. N. S. Torgersen, S. M. Schulz, R. G. Lugo, and S. Sutterlin, "Patient informed consent, ethical and legal considerations in the context of digital vulnerability with smart, cardiac implantable electronic devices," *PLOS Digit Health,* Vol. 3, No. 5, p. e0000507, May 2024, doi: 10.1371/journal.pdig.0000507

[37] J. Módné Takács and M. Pogátsnik, "The Presence of Cybersecurity Competencies in the Engineering Education of Generation Z," *Acta Polytechnica Hungarica,* Vol. 21, No. 6, pp. 107-127, 2024, doi: 10.12700/APH.21.6.2024.6.6

[38] J. Módné Takács and M. Pogátsnik, "A Comprehensive Study on Cybersecurity Awareness: Adaptation and Validation of a Questionnaire in

Hungarian Higher Technical Education," *Acta Polytechnica Hungarica,* Vol. 21, No. 10, pp. 533-552, 2024, doi: 10.12700/APH.21.10.2024.10.32

[39] I. J. Barabas, B. Merkely, I. Hartyanszky, and D. Palkovics, "Computer-aided Design and Manufacturing of a Patented, Left Ventricle Assist Device Positioning Tool – 3D Navigated Surgical Treatment of End-Stage Heart Failure," *Acta Polytechnica Hungarica,* Vol. 20, No. 8, pp. 9-25, 2023, doi: 10.12700/APH.20.8.2023.8.2

[40] T.-T. Nguyen, Q.-D. Nguyen, M.-Q. Ha, and X.-T. Hoang, "The Development of a Motion-Tracking System to Assess the Recovery Level for Stroke Survivors," *Acta Polytechnica Hungarica,* Vol. 21, No. 9, pp. 9-28, 2024, doi: 10.12700/APH.21.9.2024.9.2