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Citizens' thoughts about implantable medical devices: results of a cross-sectional survey among the general population in Hungary

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Objectives

The Medical Device Regulation (MDR 2017/745; May 2021) has raised the regulatory bar in terms of the required extent of clinical evidence for medical devices. We aimed to assess citizens' knowledge on the authorisation of implantable medical devices (IMDs) to better understand the social context in which the MDR has to be implemented.

Methods

A cross-sectional online survey was performed (year 2021) involving a sample of 1400 individuals (53.7% females) aged 40+, representative for the Hungarian general population. Health-related quality of life (EQ-5D-5L) and digital health literacy (eHEALS) were assessed. Participants' thoughts regarding IMD authorisation, data processing and security were explored with six questions ('What do you think...'; 'yes'/'no' responses). Descriptive statistics and subgroup comparisons for statistical differences were performed.

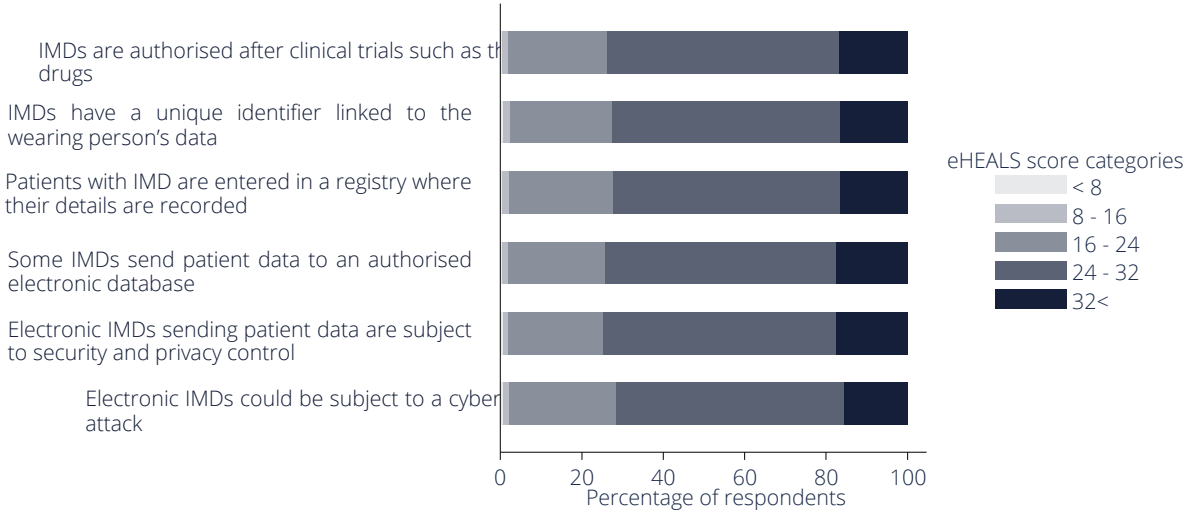
Results

The average (SD) age was 58.3 (11.1 years), EQ-5D-5L index was 0.83 (0.26) and eHEALS score was 28.1 (5.8). The share of 'yes' responses were: all IMDs are authorised after clinical trials such as the drugs: 84.7%; all IMDs have a unique identifier linked to the wearing person's data: 80.0%; patients with IMD are entered in a registry where their details are recorded: 84.6%; some IMDs send patient data to an authorised electronic database: 72.7%; electronic IMDs sending patient data are subject to security and privacy control: 71.8%; electronic IMDs could be subject to a cyber-attack: 56.2%. Participants with higher educational level and eHEALS score indicated significantly ($p<0.05$) more 'yes' responses, except the 'patient registry' and 'cyber-attack' questions, respectively. Citizens living with any IMD (N=433, 30.9%) indicated significantly ($p<0.05$) more 'yes' on the 'patient registry' question.

Conclusions

This first explorative survey revealed an overestimation of the regulatory control over IMDs and strong cyber-security concerns among the public. Educational programmes are suggested to improve citizens' knowledge on IMDs, and to put personal data protection and cyber-security issues into a realistic perspective.

Share of 'yes' responses by eHEALS score categories



References

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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