SIP Position on Digital Health: Pain Assessment and Quality Indicators

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Key recommendations

SIP calls upon EU and national policy makers to:

- Ensure effective implementation of ICD-11 by all Member States to contribute to the digitalisation of healthcare services, as these are complementary and can support each other
- Support the development and implementation of patient and clinician-friendly, interoperable, and validated digital technologies for pain assessment
- Establish pain and pain-related functioning as a quality indicator in the development of instruments of pain assessment via the use of patient-reported outcome measures (PROMs)
- Enhance the availability of, and the equal access to hybrid (face-to-face and digital) formats of pain management
- Enable the use of interoperable, standardised, secure digital health data registries, repositories, and records to facilitate exchange of cross border pain assessment data
- Allocate adequate funding to the development of translational AI and ML research in pain and pain-related functioning
- Allocate adequate funding and foster the infrastructure for digital and health literacy for all stakeholders, including clinicians and patients
- Ensure the subjective experience of pain remains an integral part of the assessment and management of pain
- Promote the exchange of best practices in digital pain and pain-related functioning assessment and management in Europe in an open format, and establish standards to ensure quality, reliable and evidence-based practices and information are shared to all

Background

In Europe[1] there are approximately 740 million people[2], most of whom experience an episode of severe pain at some point in their life. For approximately 20 percent, that pain is chronic pain. This means that, at present, 150 million people are experiencing pain across Europe, approximately equal to the population of France and Germany combined.

In 2018, SIP published its Joint Statement[3] which includes recommendations for action and collaboration by the European Commission, Member States, and civil society to reduce the societal impact of pain. These recommendations form the over-arching and guiding principles for SIP, and are divided into four categories: **health indicators, research, employment, and education**.

SIP's Joint Statement calls to explore opportunities to build on existing instruments which are available to define, establish and / or use pain and pain-related functioning as an indicator, in the assessment of healthcare systems' quality, as this will contribute to assessing and filling the data gap on the societal impact of pain[3].

The inclusion of pain as a disease under the World Health Organization (WHO) 11th revision of the International Classification of Diseases (ICD-11)[4], is a key development. In its response to the European Commission's Health Data Space Roadmap[5], SIP called for the implementation of the ICD-11 definition of pain throughout healthcare systems to improve analysis of health systems performance. This will also provide the research community with data to facilitate further clinical research. According to experts in the field, ICD-11 and the International Classification of Functioning, Disability and Health (ICF), will contribute to the transformation of healthcare in the context of the Digital Single Market[6].

The creation of a European Health Data Space[7] will ensure the appropriate use, access, and sharing of health data for healthcare delivery purposes, and will allow the use of data for research, innovation, and policymaking[8]. It is with these factors in mind that SIP outlines below several policy recommendations for European Institutions and National Governments in the area of digital health and pain.

1. Digital recording and assessment of pain

World Health Organisation (WHO) 11th revision of the International Classification of Diseases (ICD-11)

Chronic pain, along with several other types of pain, is included in the 11th revision of the International Classification of Diseases (ICD-11), as revised in June 2018. ICD-11 describes chronic primary pain as multifactorial, capturing its persistence and disruptive nature, without making assumptions about aetiology. Therefore, its implementation in all Member States is of vital importance in order for chronic pain data to become available as we move forward to more digitalised healthcare systems[3]. In addition, experts agree that ICD-11 and ICF, will play a part in transforming the healthcare system within the framework of the Digital Single Market.

Digital pain applications

Quantifying pain and pain-related functioning in a clinical environment is of upmost importance[9]. However, the likelihood of a patient receiving pharmacological pain management interventions increases if their pain level is wrongly recorded[10]. Improving our understanding of pain occurrence and treatment effectiveness, requires robust methods to assess pain and pain-related functioning using validated outcome measures. Clinicians and policy makers should be aware of the limitations of the traditional paper pain outcome measures that are still commonly used in different hospital and clinical settings[11]. These limitations are mostly based on paper pain scales being complex to use and possibly at risk of practitioner misinterpretation[12,13].

Measuring the change in pain severity and pain-related functioning on a daily basis (as well as other related symptoms) is essential in diagnosis, prognosis, and tracking response to treatment[14]. Additionally, daily reporting can help capture pain patterns better[15]. Currently, however, changes in pain severity and pain-related functioning are infrequently evaluated, and are only reviewed sometime after the start of treatment[14].

Studies have proven that patient and clinician-friendly applications can be used to monitor painful conditions and assess pain in people who suffer from moderate to severe dementia. It also provides a new way of communicating and discussing pain management[14,16]. For example, the ‘Faces Pain Scale-Revised’ tool (FPS-R, a tool for self-reporting), has proven to be a good way of measuring pain electronically, and can be recommended as means to monitor the intensity of pain[17]. In addition, recent studies confirm that using existing digital tools, such as the ‘iCanCope with Pain’ application, with suitable adaptations, can increase the capacity for self-management of young people living with musculoskeletal pain[18].

Evidence suggests that electronic visual analogue scale (eVAS) applications can be interchangeable with traditional paper visual analogue scales (pVAS) in the population[14]. The Portuguese version of the ‘Brief Pain Inventory’ has proven useful when measuring pain severity and pain interference in people with chronic kidney disease[19]. Other tools, such as ‘Pain-QuILT’ and ‘Navigate Pain’, (web-based tools), allow visual self-reporting and tracking of pain (quality, intensity, location), in the form of time-stamped records and pseudo–3D body chart avatars in different views, respectively[20]. Studies show these tools are user-friendly, quick, preferred by the majority of patients, and correlate with validated pain measures. They also have the potential to become a valuable standard component of chronic pain management[21].

Digital patient-reported outcome measures

Patient-reported outcomes measures (PROMs) help us to understand how healthcare services and procedures influence patients' health, functioning, and quality of life (QOL). They provide meaningful data on the effectiveness of care from the patient's perspective. PROMs contribute to the achievement of health system goals with valuable information that can now be collected digitally[5]. The use of validated and mobile health applications and PROMs facilitates more frequent pain severity / symptom assessments, empowers patients, and improves collection of functioning and / or QOL data. These tools could eventually become a standard, interoperable part of health care systems. They can also improve patient mobility, and the digitalisation of healthcare systems through electronic health records (EHRs)[5].

Recommendation 1: Ensure effective implementation of ICD-11 by all Member States to contribute to the digitalisation of healthcare services, as these are complementary and can support each other.

Recommendation 2: Support the development and implementation of patient and clinician-friendly, interoperable, and validated digital technologies for pain assessment.

Recommendation 3: Establish pain and pain-related functioning as a quality indicator in the development of instruments of pain assessment via the use of patient-reported outcome measures (PROMs).

2. Digital pain management (including remote and self-pain management)

Ageing populations in remote areas

Today, 20% of the European population is over 65 and it is estimated that by 2070 this figure will have risen to 30%[22]. In the same year, the number of people over 80 will have more than doubled, reaching 13% of the population[22]. The number of people potentially in need of long-term care is expected to have risen from 19.5m in 2016, to 23.6m in 2030, and up to 30.5m in 2050[22]. Healthcare professionals and patients often travel long distances to provide or access health services. Access to pain management is also more difficult for those living in remote or rural areas, in particular, for people suffering mobility issues. Everyone has the right to active and healthy ageing whilst remaining a valued contributor to their families, communities, and economies[23]. Digital technologies could facilitate more frequent collection, access, and provision of health data, information, and care, (including pain assessment and management), as well as extending the reach of healthcare to ageing and remote populations across Europe[24].

Self-management

New technologies generally have a good degree of acceptance, especially with people living with chronic pain[24]. Electronic headache diaries for example, have proven to be a practical self-management tool for adolescents and young adults. Utilisation of these diaries increases the understanding of pain and therefore the possibilities of self-management[25]. In addition, digital pain management interventions have the potential to decrease the pressure on healthcare resources by encouraging and supporting more self-management.

Recent evidence shows that educational, exercise, and psychological approaches delivered through a computer or a mobile device (e.g., as applications and text messages) are as equally effective as face-to-face approaches for managing pain intensity and disability, including for people with chronic low back pain, and hip and knee osteoarthritis[26,27,28]. For instance, 'painHealth', an Australian web-based resource (co-designed with users, and for users, to support self-management and co-care of musculoskeletal pain), has now reached 150 countries and more than one million users[29]. Following surgery, having access to high-quality rehabilitation services is of great importance. Studies show that telerehabilitation after total knee arthroplasty, for example, is just as effective as conventional in-person rehabilitation[26].

However, some 'digital-first' approaches to healthcare have been shown to potentially increase healthcare professionals' workload, (by up to 31% in the case of, for example, video consultations in general practice). It has also been recommended that digital-first (or digital-only) initiatives should not be launched unless a detailed evaluation is organised alongside[30].

Lessons learned from the COVID-19 pandemic

PAE recently conducted a survey on the impact of the COVID-19 pandemic on Europeans with chronic pain[31]. In this survey, just under half of the 970 respondents reported that obtaining healthcare and services since the beginning of the pandemic was 'difficult' or 'very difficult'. In addition, just under half of participants stated that they were receiving advice or medical appointments via telephone, and even though only ten percent had video consultations, 40% stated that would be their preferred digital management solution.

Consequently, introducing a mixed or hybrid healthcare approach (retaining face-to-face pain management appointments, complemented by digital monitoring, assessment, and management services), should be explored. As we move out of the global COVID pandemic, digital appointments should not replace in-person appointments entirely[24].

Recommendation 4: Enhance the availability of, and equal access to hybrid (face-to-face and digital) formats of pain management.

3. Clinical data registries, repositories, and records

Fragmentation of data records

A wide range of data is stored digitally, for example, advances in electronic health record systems have created well-structured digital health records, clinical notes, and medical imaging banks. These data sets play a critical role in helping healthcare professionals, patients, and researchers to improve quality of care[32]. The European Commission's Communication on the Digital Transformation of Heath, stated that "Digital solutions for health and care can increase the well-being of millions of citizens and radically change the way health and care services are delivered to patients, if designed purposefully and implemented in a cost-effective way"[5].

However, there are multiple barriers that limit the use and access to electronic health data. For example, data is often stored across different repositories, in a variety of formats, and within fragmented or siloed data systems[32]. Additionally, the quality of the data can sometimes be inconsistent, with duplicate entries and valuable data missing[32]. Globally, there are few clinical registries that collect data in real time for healthcare professionals to use simultaneously. In Europe, the 'Oslo Pain Registry' (OPR, a large registry where patient and treatment characteristics, as well as treatment and patient outcomes are analysed and recorded), has proven to be useful and effective[33]. The OPR is a great example of how valuable registries are to enable real world effectiveness assessments for people living with chronic pain conditions.

CASE STUDY

Management of post-operative pain is unsatisfactory worldwide, as more than 50% of the 240 million patients who undergo surgery each year report clinically significant pain[34]. 'PAIN OUT' is an international quality improvement and registry project that provides unique, user-friendly, web-based information intended to improve treatment of patients with post-operative pain. It is hoped that initiatives like 'PAIN OUT' will allow the use of 'real-life' data related to pain management, ultimately improving quality of care[34].

Cross border exchange of electronic health data

Access to electronic health records can facilitate health research, can aid healthcare professionals to make informed treatment decisions, and can be used to improve the quality and effectiveness of healthcare services[32,35]. Better access to health data across borders will improve the quality and continuity of care offered to EU citizens[35]. Therefore, ensuring the European Health Data Space (and similar digital health initiatives) include provisions to enable European health systems to exchange cross border data on pain assessment via standardised EHRs (and or other common tools) is key.

Privacy and security of electronic health data

Privacy and security of data is a significant issue when discussing the use of digital tools. Often, users of smartphone applications are not informed of how their data is used, stored, or managed[36]. Consequently, there are growing concerns over the lack of transparent privacy policies included in applications for certain diseases (e.g., diabetes and dementia)[37,38]. The sensitive nature of our health data means that data privacy and security should be a primary concern for both patients and clinicians, and it should be considered when making the transition into emerging tools to monitor pain progression. Smartphone application developers and digital health technology companies should therefore provide clear statements regarding their privacy policy to enable clinicians and patients to make informed decisions before they start using them.

Furthermore, as mentioned in the Commission's draft plans for a European Health Data Space[7], the data system must be built on transparent foundations that will fully protect citizens' data, and will ensure the movement of their health information as per article 20 of the General Data Protection Regulation (GDPR).

Recommendation 5: Enable the use of interoperable, standardised, secure digital health data registries, repositories, and records to facilitate exchange of cross border pain assessment data.

4. Artificial intelligence and machine learning

Emerging technologies

Artificial intelligence and machine learning (AI/ML) technologies are being used to improve the understanding, diagnosis, and management of pain and pain-related functioning. Studies show that even though self-reporting remains optimal for pain assessment, ML may help when classifying pain disorders like chronic back pain or fibromyalgia[39]. Recent studies suggest that computer-based classification methods (assessing pain status as either better, same, or worse), could be reliably determined[40].

Algorithms to support emerging technologies can be fed with two types of data: (i) self-reported data from EHRs, (such as pain, disability, medical history, psychological factors, and imaging results); and (ii) advanced brain and blood imaging techniques.

In the future, it is hoped that self-reported data from electronic pain records could predict prognosis in patients with pain and inform treatment design and pain prevention[41]. For instance, evidence suggests that using ML based on electroencephalography (EEG) could predict analgesic response before the administration of drugs[42]. Recent advances in ML have triggered publications such as the Joint Research Centre (JRC) Technical Report on the Robustness and Explainability of Artificial Intelligence[43]. This emphasises the need to establish good practices and threat-driven pathways in order to increase trust in AI systems, as well as the need for transparency regarding computer-based decisions.

AI and ML technologies could also be used to improve the understanding of pain mechanisms[44]. The integration of ML with clinical decision support tools, (such as diagnostic support), may offer healthcare professionals targeted and timely information which can improve and aid clinical decisions. Nevertheless, while these studies contribute to overall knowledge, more evidence is needed in the field to make AI and ML an integral part of healthcare practice.

Recommendation 6: Allocate adequate funding to the development of translational AI and ML research in pain and pain-related functioning.

Recommendation 7: Allocate adequate funding and foster the infrastructure for digital and health literacy for all stakeholders, including clinicians and patients.

5. The subjective experience of pain

Ensuring the subjective experience of pain remains integral to pain assessment and management

Pain is a subjective, personal experience and as such, reporting and assessment practices cannot be limited to markers from tools that can only capture specific dimensions of pain. Evidence shows the difficulty in translating the results of laboratory studies of the nociceptive system into conclusions about real-world experiences of pain, and the challenge of translating brain decoding into real-world clinical applications[41]. Additionally, ML may use algorithms based on biased data, leading to social and economic inequalities in healthcare services. In order to mitigate these issues, there should not be a reliance on these technologies in isolation[45]. Furthermore, the use of machine learning algorithms to confirm if a person is in pain, or as a form of illness or disability clarification, cannot replace the reporting and assessment of the subjective personal experience of pain.

Recommendation 8: Ensure the subjective experience of pain remains an integral part of the assessment and management of pain.

6. Exchange of best practice

The WHO's Global Strategy on Digital Health 2020-2025 strategic objective number three[46] ('Strengthen governance of digital health at global, regional, and national levels') highlights the importance of promoting the exchange of best practices, good governance, infrastructure architecture, programme management, and use of standards to promote interoperability for digital health. Initiatives such as the newly formed Scientific Research Network PAIN (funded by the Research Foundation – Flanders (FWO)[47]) is one such example. In this project, countries like Canada, the United States and Portugal, amongst others, will promote strategic collaborations and enhance new opportunities for clinical and translational research.

Additionally, the European Commission's Communication on the Digital Transformation of Health[6], acknowledges that health data (which can sometimes be available and managed in different forms depending on the country) is a key enabler for digital transformation. It also states that healthcare authorities across Europe often face common challenges, which can be best addressed jointly through the exchange of best practices. Finally, there have been a number of best practices on digital health applications and services cited in this paper. As part of the development and use of new technologies and strategies within the digital health framework, SIP would like to encourage the sharing of best practices and good governance between EU Member States.

Recommendation 9: Promote the exchange of best practices in digital pain and pain-related functioning assessment and management in Europe in an open format, and establish standards to ensure quality, reliable and evidence-based practices and information are shared to all.

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SIP remains available for further discussions with the European Commission, the Members of the European Parliament, the Council, digital health technology developers, and civil society stakeholders for future cooperation to ensure our recommendations are implemented in the area of digital health and pain.

About SIP

The 'Societal Impact of Pain' (SIP) platform is a multi-stakeholder partnership led by the European Pain Federation EFIC and Pain Alliance Europe (PAE), which aims to **raise awareness of pain** and **change pain policies**.

SIP provides opportunities for discussion for health care professionals, pain advocacy groups, politicians, healthcare insurance providers, representatives of health authorities, regulators, and budget holders.

The scientific framework of the SIP platform is under the responsibility of EFIC and the strategic direction of the project is defined by both partners. The pharmaceutical company Grünenthal GmbH is the main sponsor of the Societal Impact of Pain (SIP) platform.

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Sources

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[1] Note: data taking from 37 countries, absent in Andorra, Armenia, Azerbaijan, Belarus, Georgia, Iceland, Liechtenstein, Luxembourg, Malta, Monaco, and the Vatican City.

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