



Organizational impact study of Implicity RM platform ⁽¹⁾ for the remote monitoring of patients with cardiac implantable electronic devices: results from a French multi-center user-centric survey.



Context

Although Remote Monitoring (RM) for CIED patients is recommended by international guidelines, its daily adoption remains low ⁽²⁾, because of a rising number of implanted patients ⁽³⁾ and the complex management required ⁽⁴⁾.

In 2023, the international expert consensus issued a statement on Practical Management of the Remote Device Clinic, highlighting RM's organizational benefits for follow-up and patient care. They noted that successful RM implementation requires dedicated infrastructure and teams, and that third-party resources can provide financial and operational advantages. A third-party platform is an external system that integrates data from various medical devices and manufacturers and provides a unified interface for healthcare providers. Consequently, using vendor-neutral third-party platforms is now a 2a recommendation in the 2023 Expert Consensus from HRS and EHRA ⁽⁵⁾.

In France, to address the lack of specific methodology and guidelines to assess the organizational impacts of a health technology, the French National Authority for Health (HAS) published a guide in December 2020. This guide offers a framework for understanding and documenting these impacts. A recent study showed the value of this framework in evaluating RM solutions and highlighted the diverse organizational structures that emerge with RM implementation ⁽⁶⁾.

The HAS framework guided the survey methods and analysis of the organizational impacts of the vendor-neutral Implicity CIED RM platform, available in France since 2018.



Objective

The objective of the survey was to demonstrate the positive impacts of Implicity RM platform compared to conventional platforms in France on 8 macro criteria from the HAS guide.

The detailed criteria are given in the "results" box.



Method



• In absence of a structured framework for qualitative evaluation of organizational impacts from Healthcare Professionals (HCP), Implicity created its own user survey to evaluate the organizational impacts of Implicity RM platform.

• The survey was sent to users from French centers who logged into the Implicity RM platform for CIED patients at least once in the 2 months prior.

• The survey was composed of 2 parts :
1 - General information about the respondent.
2 - Specific questions for respondents that used to monitor their patients on conventional platforms. ("Subgroup RM Before")

• Data was collected between April 26th & May 24th 2023.

• Subgroup RM before was asked **26 statements** using a rate scale inspired by the Likert Scale method.

• Answers from the "Subgroup RM Before" were gathered into 5 groups :
 - R+ (Strongly agree & agree),
 - R- (strongly disagree & disagree),
 - Neutral,
 - No opinion,
 - All (R+;R- & neutral).

• % of R+ = R+ / All was calculated on the subgroup RM before.

• The proportions of R+ and R- of the Subgroup RM BEFORE were compared using a Khi-squared test. A p-value < 0.05 was considered as statistically significant.



Results

According to the survey respondents, compared to conventional RM platforms, Implicity has positive impacts on the following criteria:

Criterion 1.3: Modifies process timing or content of the care process



Criterion 2.1: Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care

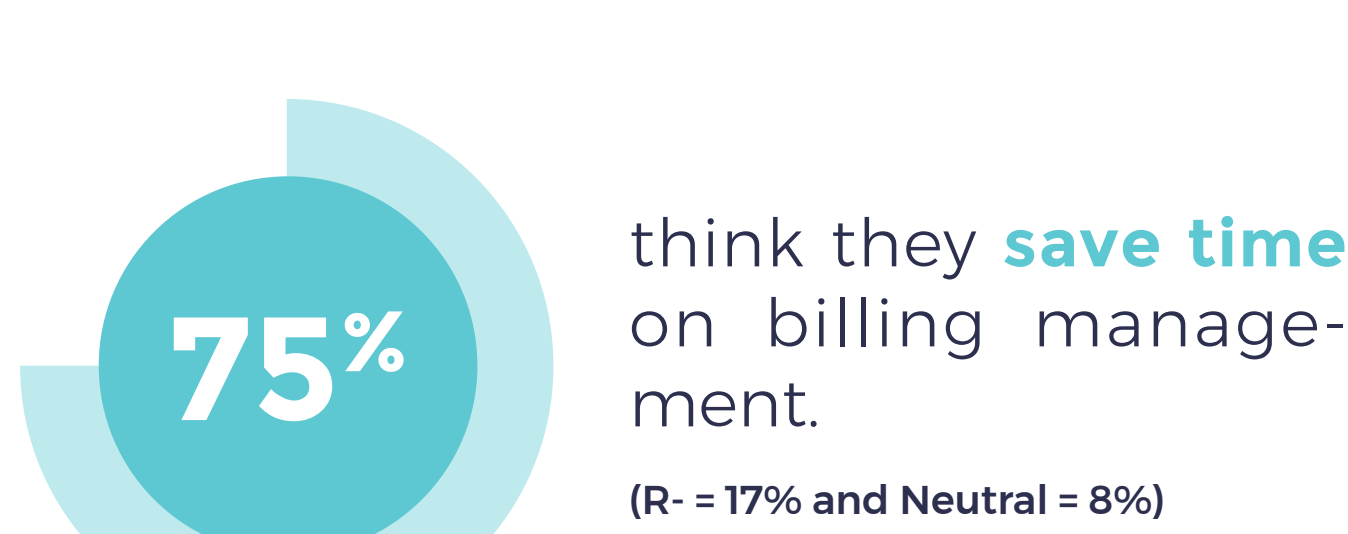


Criterion 2.2: Modifies the ability to share and transfer skills, knowledge, and know-how with other stakeholders

Criterion 2.3: Modifies scheduling and planning capacities for health care services or the patient or carer



Criterion 2.3

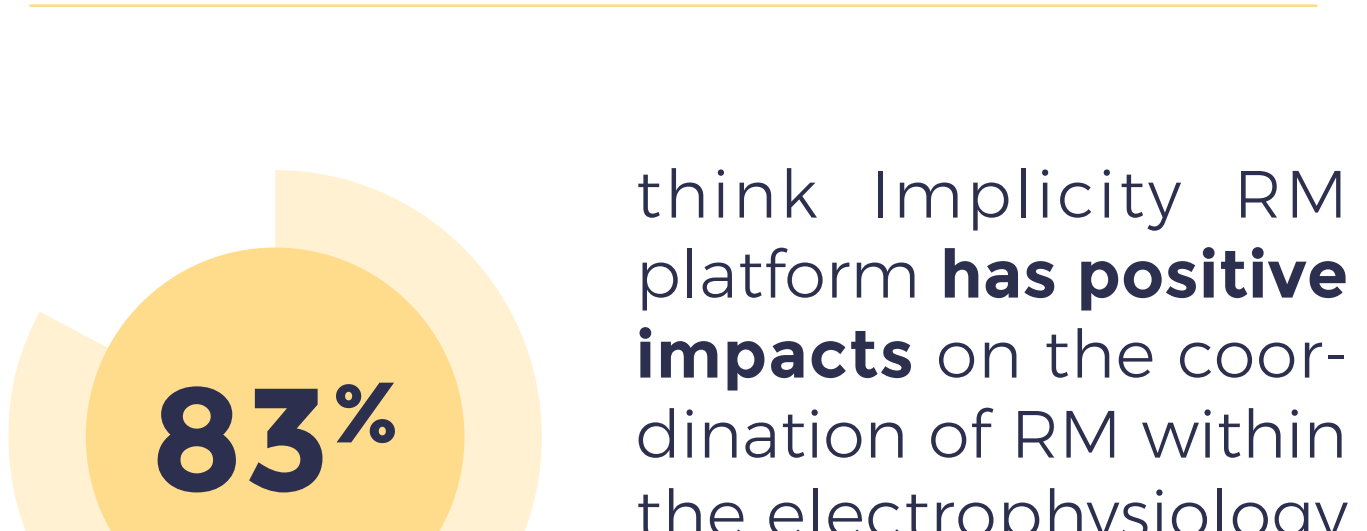


Criterion 2.3



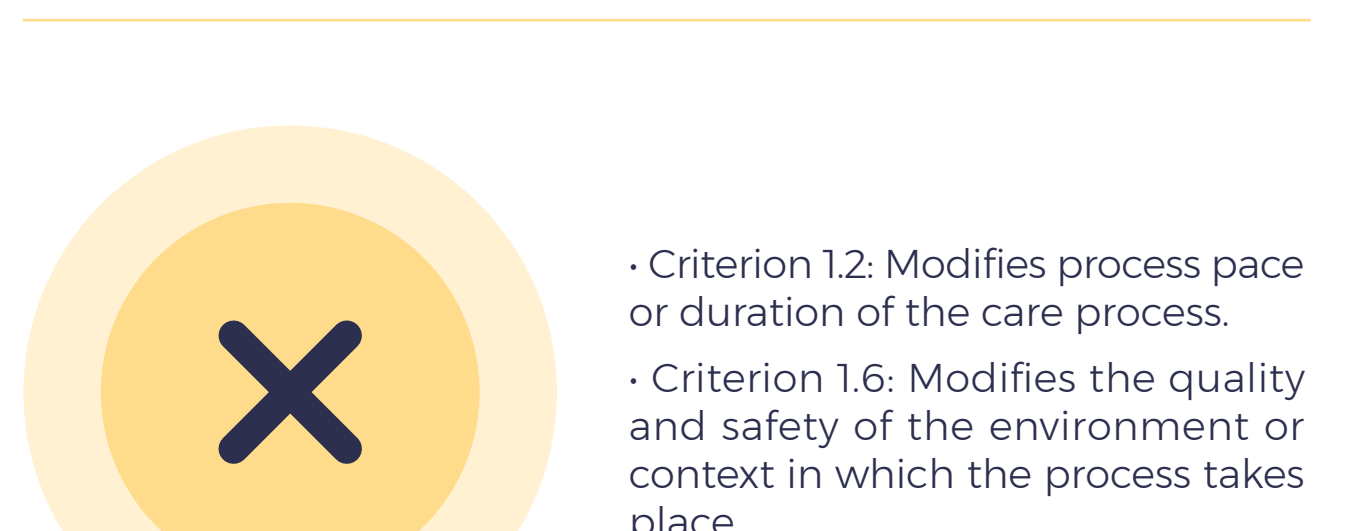
Criterion 2.4: Modifies scheduling and planning capabilities between care structures or combinations of stakeholders

Criterion 3.1: Impact on community in terms of health and safety



Criterion 3.1

The study failed to conclude on the organizational impacts of Implicity RM platform on the following criteria



Conclusion

The study showed positive impacts on 6 criteria of the HAS body.

These positive results regarding the Implicity RM platform corroborate the recent expert consensus statement released by HRS/EHRA/APHRS/LAHRs in 2023 which highlights in detail the importance of third-party resources for remote monitoring organizational efficiency.

The use of third-party agnostic platforms dedicated to CIED RM is from now officially recommended as a standard of care by the international CIED RM expert community.

Together with other studies, this analysis of the Implicity RM platform was selected by HAS, the French HTA body ⁽⁷⁾ to recognize the positive organizational impact of Implicity's RM platform for remote monitoring of patients with defibrillators or pacemakers.

Sources
 (1) IM009 is a CE marked class I medical device (MDD), see the instructions for use for more information.
 (2) Dubner, S., Auricchio, A., Steinberg, J. S., et al. "ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)." Ann Noninvasive Electrocardiol 2012. 17(1): 36-56.
 (3) Massaro, C., Diemberger, I., Ziacchi, M., et al. "A Historical Perspective of Cardiac Implantable Electronic Device Infection: How a Menace Can Drive Technological and Clinical Improvement." Hearts 2021. 2(2): 202-212.
 (4) Seiler, A., Biundo, E., Di Bacco, M., et al. "Clinic time required for remote and in-person management of patients with cardiac devices: Time and motion workflow evaluation." JMIR Cardio 2021. 5(2): e27720.
 (5) Ferrick, A. M., Raj, S. R., Deneke, T., et al. "2023 HRS/EHRA/APHRS/LAHRs Expert consensus statement on practical management of the remote device clinic." Europace 2023. 25(5): euad123.
 (6) Alami, S., et al. (2023). "Organisational impact of a remote patient monitoring system for heart joint management: The experience of 29 cardiology departments in France." Int J Environ Res Public Health 20(5): 4366.
 (7) https://www.has-sante.fr/jcms/p_3545270/fr/implicity-im009

