

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

Date	Version	Description
22/12/2023	1.5	First version

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1. Scope

The scope of this report is to present and analyze the results of the “Organizational impact survey” carried out between April and May 2023 in order to assess the organizational impacts of the Implicity platform for the remote monitoring (RM) of patients with cardiac implantable electronic devices (CIED) from its French users’ perspective.

2. Background

Mortality and morbidity impacts of RM for patients with CIED have been widely studied (Varma, Piccini et al. 2015). However, although RM of CIED patients is recognized by international guidelines as a standard, its adoption in daily practice remains low (Dubner, Auricchio et al. 2012), while the number of implanted patients is constantly increasing (Massaro, Diemberger et al. 2021).

An observational study (Seiler, Biundo et al. 2021) confirmed the complexity of the management of patients with CIEDs. The associated workflows require significant clinical and administrative staff time across in-person clinic visits, remote transmission review, and other patient management tasks.

The international expert consensus statement on Practical Management of the Remote Device Clinic published in May 2023 gives a greater emphasis on the organizational benefits of RM, especially on follow-up optimization and patient management, but reminds us that RM requires organizational models and infrastructure and dedicated teams in order to allow clinical benefits. It also mentions that the use of third-party resources may offer financial and practical benefits for dealing with increased device clinic volume. As such, while the use of vendor-neutral third-party platforms is gaining interest and adoption in the USA and France, it is now a 2a recommendation in the 2023 Expert consensus from the HRS and EHRA (Ferrick, Raj et al. 2023).

No structured study has been conducted in Europe to assess the magnitude of organizational impacts of such vendor-neutral platforms for CIED RM, especially by processing the outcomes reported by the healthcare professionals using those platforms collected through a survey.

In France, to address the lack of specific methodology and guidelines for the assessment the organizational impacts of a health technology, the French National Authority for Health (HAS) published a guide in December 2020¹ whose purpose is to “*clarify the aspects associated with the organizational impacts of a health technology by drawing up a map aimed at both defining these impacts and at proposing criteria to assist with their documentation*”. This comprehensive organizational impact map was used in a recent French study which presented the results of a survey on the organizational impacts of a heart failure RM solution (Alami et al. 2023). This study highlighted the variety of organizational structures, which tended to structure with the use of the RM solution, and confirmed the interest in documenting the organizational impacts of a RM solution by using this map.

The HAS map was used as a guide and support for building the methods and analyzing the results of a survey aiming at assessing the organizational impacts of the vendor-neutral Implicity CIED RM platform, commercialized in France since 2018.

¹https://www.has-sante.fr/upload/docs/application/pdf/2021-04/organisational_impact_map_for_health_technology_assessment.pdf (Opened for the last time on 30th June 2023)

3. Objectives

The objective of the study was to evaluate the organizational impacts of Implicit RM platform on routine care practice compared to the use of manufacturers' portals (Carelink for Medtronic, Latitude for Boston Scientific, Merlin for Abbott, Home Monitoring for Biotronik, Smartview for MicroPort) in France, from the perspective of the professionals using the platform. This study seeks to demonstrate the positive impacts of Implicit RM platform on the following criteria from the HAS map:

- **Macroriterion 1:** Impacts of the health technology on the care PROCESS
 - *Criterion 1.2:* Modifies process pace or duration of the care process
 - *Criterion 1.3:* Modifies process timing or content of the care process
 - *Criterion 1.6:* Modifies the quality and safety of the environment or context in which the process takes place
- **Macroriterion 2:** Impacts of the health technology on the CAPABILITIES and SKILLS required of stakeholders to implement 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 2.4:* Modifies scheduling and planning capabilities between care structures or combinations of stakeholders
- **Macroriterion 3:** Impacts of the health technology on SOCIETY or the COMMUNITY
 - *Criterion 3.1:* Impact on community in terms of health and safety.

4. Methods

a. Survey design

A survey - intended to be addressed to the routine users of Implicit platform - was created (see [Appendix 1](#)) in order to evaluate the level of impact for each of the selected criteria reported in the section above.

This survey was composed of two parts:

- **1st part:** general information about the respondent: contact, function (nurse, doctor, other); duration of use of the platform (less than 3 months, from 3 months to 1 year, more than 1 year); number of patients remotely monitored; brands of CIED remotely followed in the center (Medtronic, Boston Scientific, Abbott, Biotronik, Microport). The last questions of this part asked whether they used to remotely monitor their patients before using Implicit.
- **2nd part:** the following part of the survey was only addressed to the respondents who answered "yes" to the last 1st part question: "Did you remotely monitor CIED patients before you started using Implicit?"

Since the survey was sent to French recipients, the questions were asked in French. For the homogeneity of this report, the same questions were translated into English. The correspondence between French and English questions can be found in [Appendix 1](#).

Users who did not remotely monitor CIED patients before they started using Implicitly are referred as “Subgroup NO RM BEFORE” while users who remotely monitored CIED patients before starting using Implicitly referred as “Subgroup RM BEFORE” in the remainder of this document.

Subgroup RM BEFORE users were asked to give their opinion on 26 statements, by using a rate scale inspired by the Likert Scale method, one of the first validated psychometric methods developed to assess surveys in Human Sciences (Likert, 1932 & Sullivan et al. 2013). The Likert scale is a commonly used rating scale in social science research and surveys. It is designed to measure attitudes, opinions, or perceptions of individuals regarding a particular topic or statement. The scale typically consists of a series of statements or items, and respondents are asked to indicate their level of agreement or disagreement with each statement. The Likert scale typically uses a 5-point or 7-point scale, ranging from “Strongly agree” to “Strongly disagree” or from “Strongly satisfied” to “Strongly dissatisfied”. The exact response options may vary depending on the study or survey design. In medicine, most studies use the Likert scale to evaluate the satisfaction of patients or Healthcare professionals.²

The following rate scale has been applied:

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- No opinion.

Although many questionnaires for the evaluation of patients Quality of Life (QoL) exist, there is a lack of uniformized questionnaires on the organizational impact of Digital Health solutions for healthcare professionals. In absence of such a structured framework to answer HAS map, Implicitly created its own survey for its users to evaluate the organizational impacts of Implicitly RM platform on care processes, stakeholders capabilities and skills and on society.

b. Implicitly RM platform

The evaluated solution is the Implicitly RM platform, a vendor-neutral and alert-centric CIED RM solution, which:

- Collects, hosts and displays data from CIEDs and alerts from the IM009 Alert management solution (rhythm & physiological alerts, security alerts, disconnection alerts), in a vendor-neutral and ergonomic way, by allowing the RM of any type of CIED whatever the model and brand, in a single interface;
- Performs the processing of the data and alerts transmitted by the CIEDs through a software-as-a-medical device (SaMD), the IM009 Alert management solution, that is designed to (1) categorize observations generated by CIEDs (2) create relevant (“smart”) observations based on signals recorded by the devices and (3) suggest hiding observations that are not clinically relevant, based on clinical data (e.g. AF alert in an already anticoagulated patient);
- Collects, hosts and displays clinical and medico-administrative data filled in by the healthcare team and/or pickup up via interoperability with the hospital’s electronic health records;

² <https://pubmed.ncbi.nlm.nih.gov/33284318/> Accessed July 19th,2023

<https://pubmed.ncbi.nlm.nih.gov/25796117/> Accessed July 19th,2023

<https://pubmed.ncbi.nlm.nih.gov/33551487/> Accessed July 19th,2023

- Allows technical and administrative support for tasks related to remote patient monitoring (e.g. collaboration features, medical report generation, billing).

The Implicity platform aims at standardizing, contextualizing, and prioritizing the information from CIEDs made available to healthcare teams.

The solution is called “Implicity RM platform” and therefore referred as such in this document.

c. User selection criteria

The term "user" refers to healthcare professionals (physicians and nurses) using Implicity RM platform, and the term "center" refers to the legal entity that contracted with Implicity as subcontractor to provide the platform (aka ‘customer’). Based on that, the following terms have been defined for ease of reading:

- Implicity users who received the survey are called “user recipients”
- Implicity users who answered the survey are called “user respondents”
- Implicity centers with at least one affiliated user recipient are called “center recipients”
- Implicity centers with at least one affiliated user respondent are called “center respondents”.

The user recipients were extracted from Implicity RM platform user base (medical & non-medical professions such as secretary) according to the following criteria:

- Geography: survey recipients affiliated with French centers
- Product: Implicity RM platform for CIED patients
- Activity: “Active users” of the platform were defined as those who had logged on to the platform at least once in the two months prior to sending the survey for the first time. Hypothesis has been made that a user who has not logged for 2 months cannot be considered as a regular user. Hence the choice of looking at users who logged at least once during the 2 months prior to the survey. It is not correlated to the duration of their usage of the platform.

The survey was sent to all of the 331 users that met the previous criteria: 165 physicians, 98 nurses and 68 other functions (e.g. clinical research associate, secretary) in 75 centers including:

- “Public sector” facilities; They will be referred as “public hospitals” in the remainder of the report;
- “Private sector for-profit” facilities: for healthcare professionals working without any partners or government sponsorship. They will be referred as “private practices” in the remainder of the report;
- “Private sector non-profit” facilities: at Implicity, the only private customers with non-lucrative goals are ESPIC: (Etablissement de Santé Privé d'Intérêt Collectif: status created by the French Law). They will be thus referred as “ESPIC” in the remainder of the report.

This segmentation by type of centers comes from the dedicated sheet published by the “Direction de la recherche, des études, de l’Evaluation et des Statistiques” (DRESS) on the main categories of healthcare facilities in France³.

³ [Fiche 01 - Les grandes categories d'établissements de santé, édition 2022, DREES](#) Accessed July 19th, 2023

d. Data collection

Data was collected through an online survey tool between April 26th and May 24th, 2023. The questionnaire was first sent on April 26th. The user recipients that did not answer were contacted again on May 4th and 18th. The questionnaire was closed on May 24th.

e. Data processing and statistics

To ensure the significance of the results, we have gathered the response types into 5 groups.

- R+: “Strongly agree” and “Agree”
- R-: “Strongly disagree” and “Disagree”
- Neutral
- No opinion
- All: R+, R- & neutral.

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. The statistical analysis was performed using XLSTAT 2023 software (Addinsoft, Paris, France).

The percentage of R+ and R- responses excluded the “no opinion”.

- %R+ = R+ / All
- %R- = R- / All

f. Interpretation of the results

The results were interpreted using the following scale:

75% or more of R+	Strong positive impact
Between 50% & 75% of R+	Moderate positive impact
Between 50% & 75% of R-	Moderate negative impact
75% or more of R-	Strong negative impact

Table 1: Classification of Implicity's impacts

To facilitate the understanding of this study, the statistics on user respondents’ answers were classified according to HAS macrocriteria. Further details on the correspondence between the questions and those macro criteria will be justified in the discussion.

5. Results

a. Respondent characteristics

The survey was completed by 45 user respondents from 31 different centers: 25 user respondents belonged to Subgroup NO RM BEFORE (users who did not remotely monitor CIED patients before they started using Implicity) while 20 belonged to Subgroup RM BEFORE (users who remotely monitored CIED patients before starting using Implicity). A total of 41.3% of center recipients were center respondents.

User recipients and respondents were classified according to their function to assess the proportion of user respondents per function type in Table 2.

Type of function	Number of user recipients	Number of user respondents			Rate of response
		Subgroup NO RM BEFORE	Subgroup RM BEFORE	TOTAL	
Practitioners	165	2	9	11	6,7%
Nurses	98	21	10	31	31,6%
Others	68	2	1	3	4,4%

Table 2: Type of function of the user recipients and respondents.

Although a large number of user recipients were physicians, the population that responded the most were nurses (31.6%), who are the most frequent users of Implicit RM platform.

Table 3 describes the statistics related to the type of center and the mean number of RM patients by type of center.

Type of centers covered by the survey	Mean number of RM patients by type of center respondent	Number of center recipients	Number of center respondents	Rate of response
Private practices	300	41	9	22,0%
Public hospitals	1116	29	20	69,0%
ESPIC	2610	5	2	40,0%

Table 3: Characteristics of the centers covered by the survey.

b. Subgroup-NO RM BEFORE answers

The objective of the study is to compare the organizational impacts of using Implicit RM platform compared to using manufacturers portals for CIED RM.

Respondents of Subgroup NO RM BEFORE did not perform RM with manufacturers portals. Their answers are therefore not exploitable in this study.

c. Statistical analysis of Subgroup RM BEFORE

Here below we present the statistical analysis by answer and by respondent.

Statistics on user respondents' answers to Implicit's statements

Among the 20 user respondents of Subgroup RM BEFORE, 95% of them used to remotely monitor patients implanted with devices from all five manufacturers (Medtronic, Boston Scientific, Abbott, Biotronik, Microport) while 5% (1 user respondent) only monitored patients implanted with devices from 3 of them (Medtronic, Abbott and Microport).

Statistics on users respondents' answers to Implicit's statements of Subgroup RM BEFORE are shown on figures 1 to 8.

In the figures below, only answers from groups "R+" and "R-" were used for Khi-squared test. The group "No opinion" is not showed in the charts. A complete table with the number of respondents among each group (strongly disagree, disagree, neutral, agree, strongly disagree & no opinion) can be found in [Appendix 2](#).

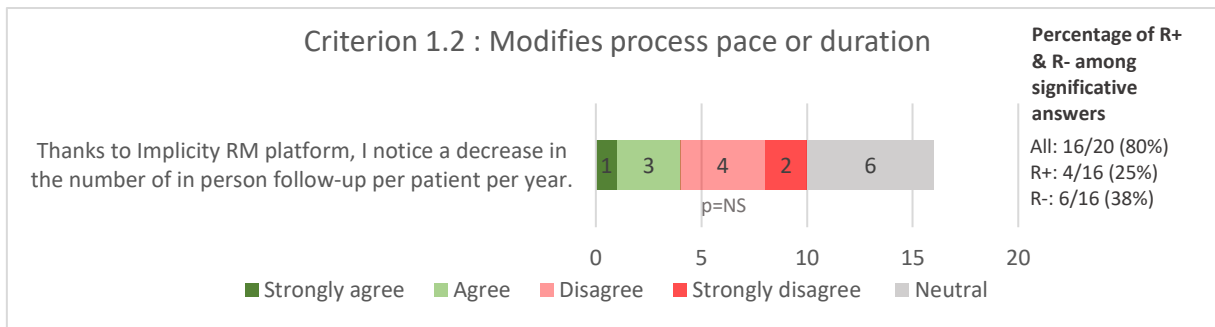


Figure 1: Answers to the statements associated to criterion 1.2 of Subgroup RM BEFORE

There were no significant results on the impact of Implicit RM platform on the number of in person follow-ups per patient per year.

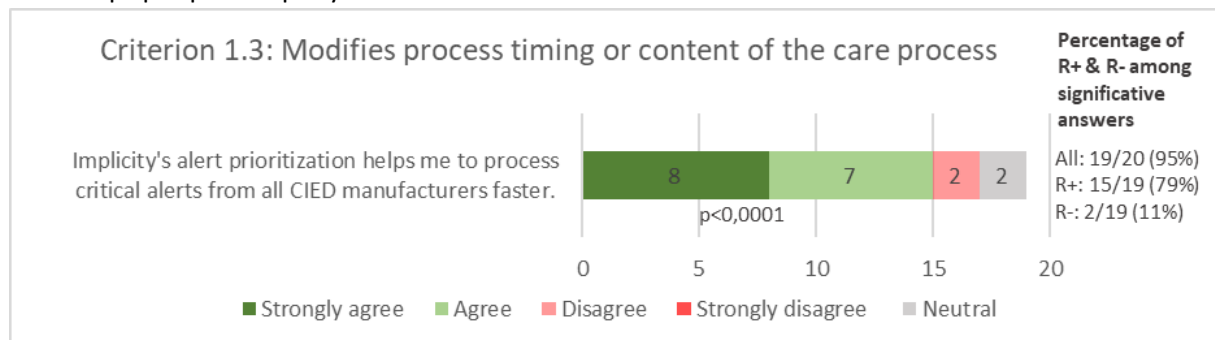


Figure 2: Answers to the statements associated to criterion 1.3 of Subgroup RM BEFORE

Implicit RM platform has positive impacts on the time spent on processing all CIED alerts.

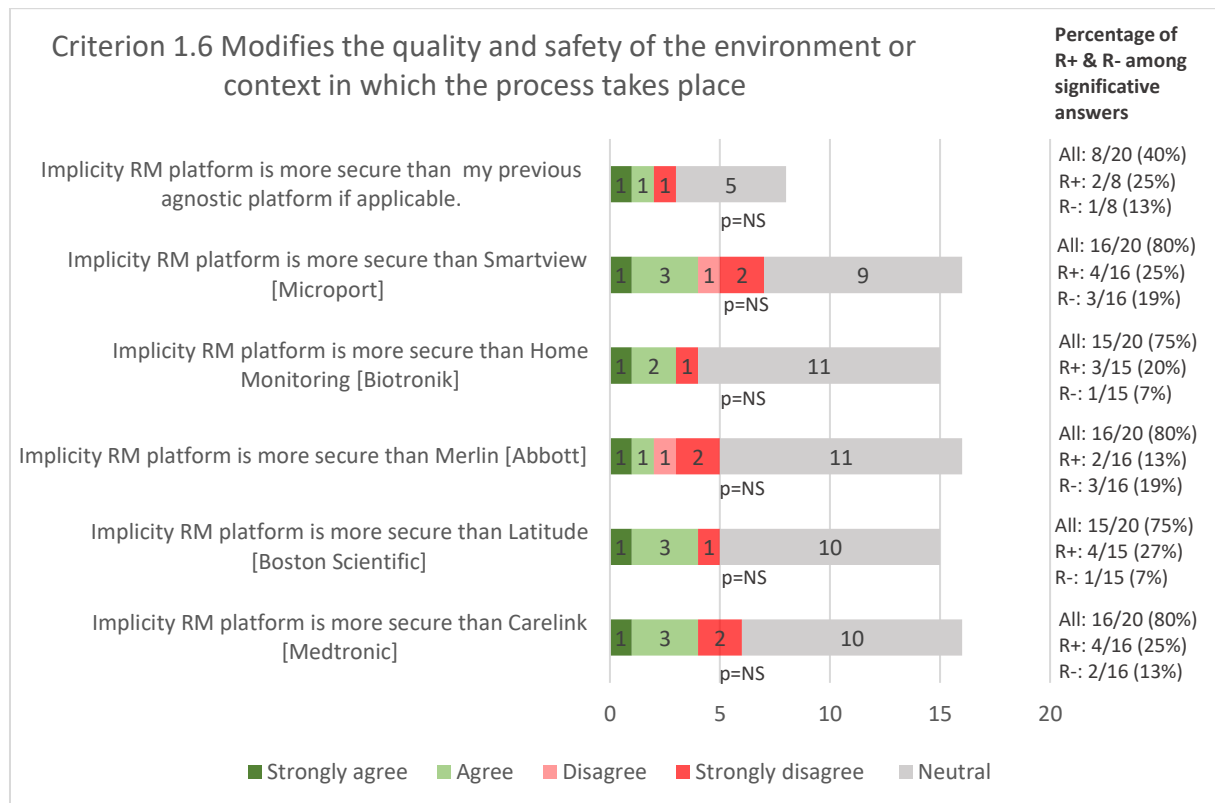


Figure 3: Answers to the statements associated to criterion 1.6 of Subgroup RM BEFORE

Most user respondents answered “Neutral” to the questions “Implicitly is more secure than (...)”. The results were therefore non-significant to show a superiority of Implicitly RM platform security compared to the manufacturer portals or any previous agnostic platform.

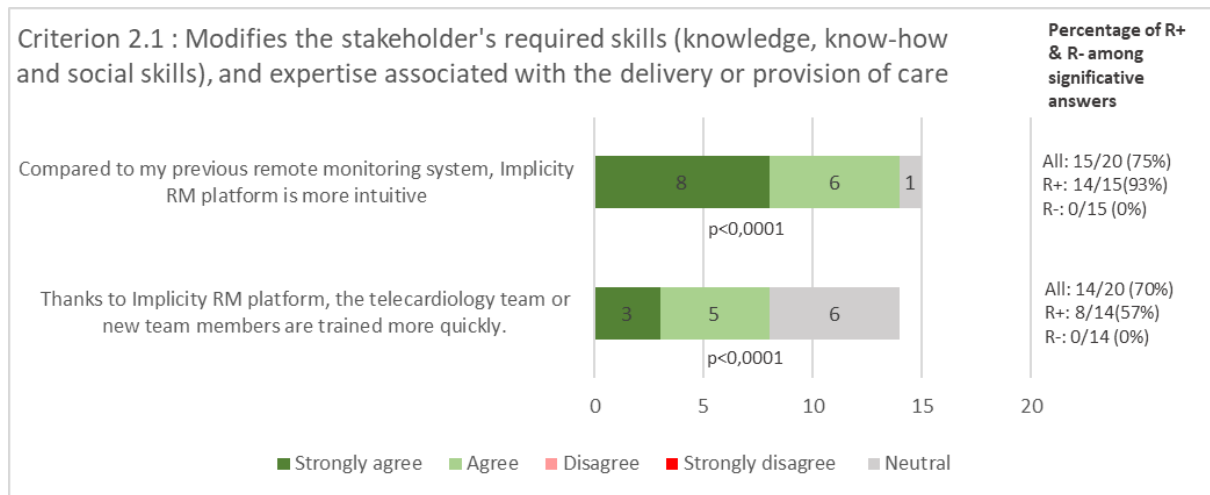


Figure 4: Answers to the statements associated to criterion 2.1 of Subgroup RM BEFORE

Implicitly RM Platform has positive impacts on the time spent training new team members. A significant amount of user respondents think that Implicitly RM platform is more intuitive.

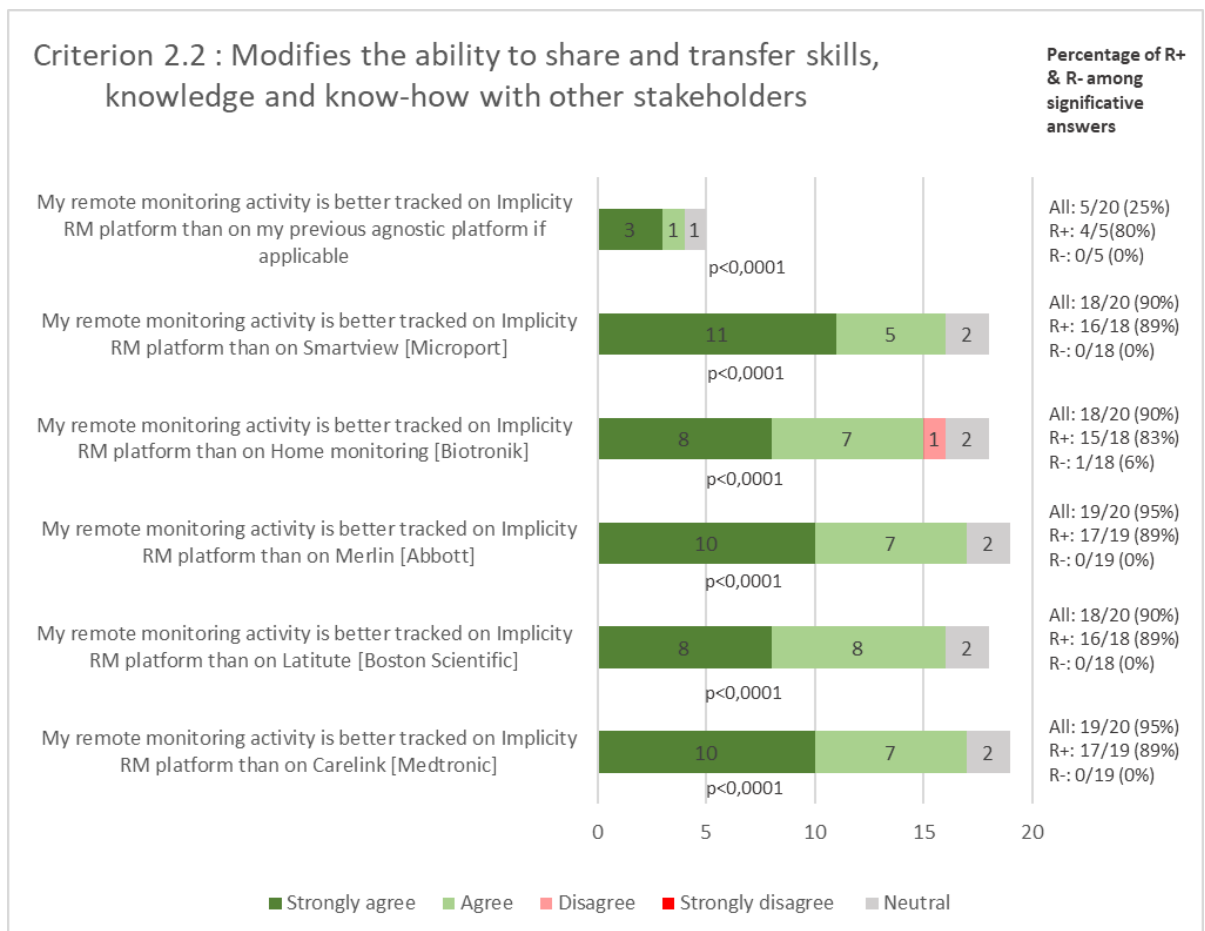


Figure 5: Answers to the statements associated to criterion 2.2 of Subgroup RM BEFORE

Implicitly RM platform has positive impacts on the tracking of RM activity compared to the manufacturer portals or any previous agnostic platform.

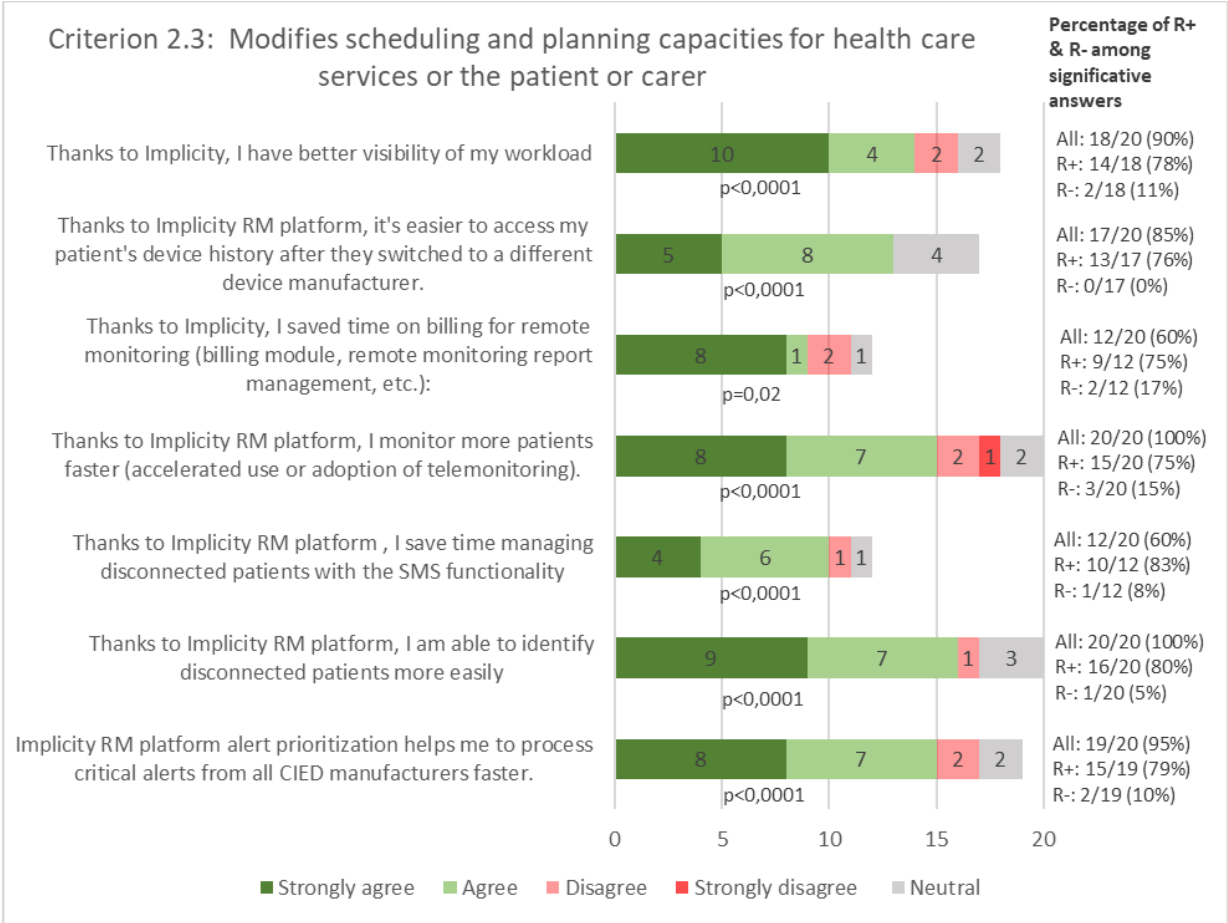


Figure 6: Answers to the statements associated to criterion 2.3 of Subgroup RM BEFORE

Implicitly RM platform has positive impacts on:

- The visibility of CIED RM teams on their workload
- The accessibility to patient’s device history after they switched to a different device manufacturer
- The time spent on billing management
- The use and adoption of RM
- The identification of disconnected patients
- The time gain on managing disconnected patients
- The time spent on processing critical alerts.

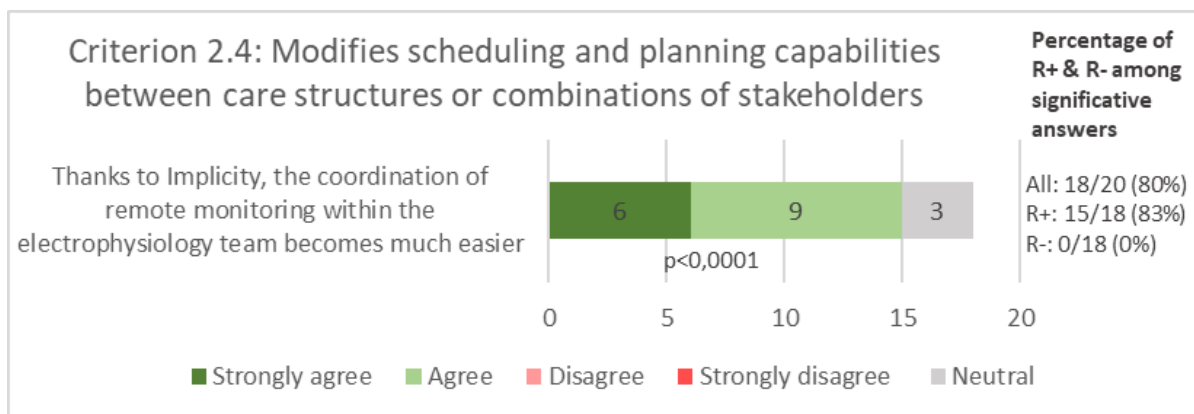


Figure 7: Answers to the statements associated to criterion 2.4 of Subgroup RM BEFORE

Implicity RM platform has positive impacts on the coordination of RM within the electrophysiology team.

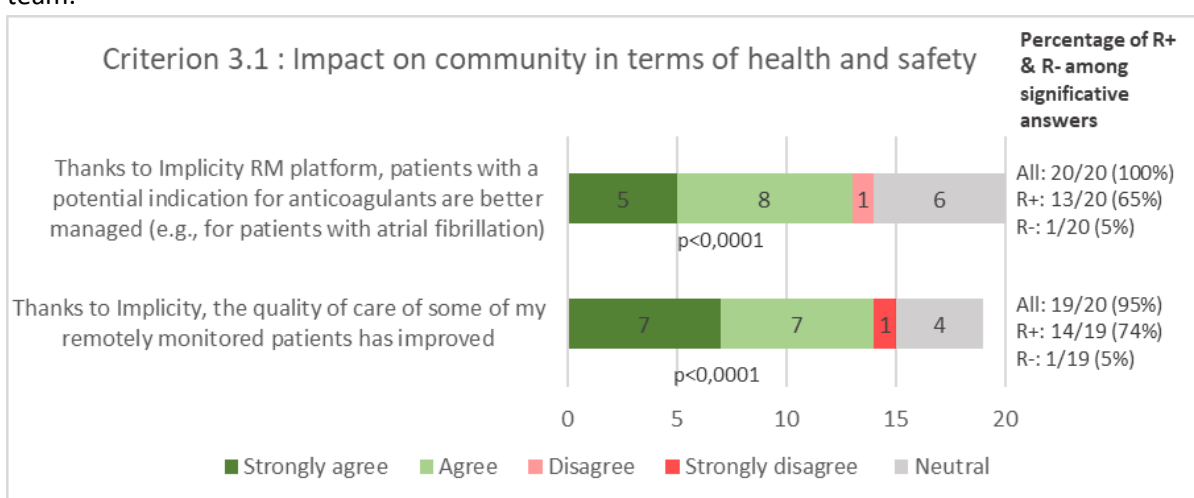


Figure 8: Answers to the statements associated to criterion.1 of Subgroup RM BEFORE

Implicity RM Platform has positive impacts on:

- The quality of the management of anticoagulants
- The quality of care of some patients.

Statistics on R+ & R- answers by user respondents of subgroup RM Before

Overall, every respondent of the subgroup RM BEFORE answered at least 5 “strongly agree” or “agree” on the 26 statements of the survey. The positive answers of the respondents that had only 5 R+ were mainly related to the Macro Criterion 2.3 “Modifies scheduling and planning capacities for health care services or the patient or carer”.

The median, first and third quartile for the number of R+ & R- answers per respondent are presented in the table below.

	Number of R+ by respondent	Number of R- by respondent
Q1 (25%)	12	0
Median	15	1
Q3 (75%)	17	3

Table 4: Q1, Median & Q3 of R+ & R- answers per respondent

For R+ answers, the median respondent agreed with more than 57% (15/26) of Implicity's statements while for R- answers, the median respondent disagreed with only 1 statement.

6. Discussion

The survey provided a comprehensive description of organizational impacts of Implicity RM platform on its users' daily practice for the RM of CIED patients. In the 45 user respondents, 25 belonged to Subgroup NO RM BEFORE while 20 belonged to Subgroup RM BEFORE. The subgroup NO RM BEFORE will not be mentioned in the discussion since their results were not exploitable.

a) Discussion on the survey results showing a significant p value ($p < 0,05$)

The following table classifies the impacts of Implicity RM platform according to the criteria described by the HAS map and to [table 1 - classification of results](#):

HAS criterion	Related positive impacts of Implicity RM platform	Robustness of the Impact
<i>Criterion 1.3:</i> Modifies process timing or content of the care process.	<ul style="list-style-type: none"> • The time spent on processing all alert. 	Strong Positive Impact
<i>Criterion 2.1:</i> Modifies the stakeholder's required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care	<ul style="list-style-type: none"> • The time spent training new team members 	Moderate positive Impact
	<ul style="list-style-type: none"> • The platform is more intuitive 	Strong Positive Impact
<i>Criterion 2.2:</i> Modifies the ability to share and transfer skills, knowledge and know-how with other stakeholders	<ul style="list-style-type: none"> • The tracking of RM activity compared to the manufacturer portals or any previous agnostic platform 	Strong Positive Impact
<i>Criterion 2.3:</i> Modifies scheduling and planning capacities for health care services or the patient or carer	<ul style="list-style-type: none"> • The time spent on processing critical alert. • The time gain on managing disconnected patients; • The identification of disconnected patients • The use and adoption of RM • The time spent for billing • The visibility of CIED RM teams on their workload; • The accessibility to patient's device history after they switched to a different device manufacturer 	Strong Positive Impact
<i>Criterion 2.4:</i> Modifies scheduling and planning capabilities between care structures or combinations of stakeholders	<ul style="list-style-type: none"> • The coordination of remote monitoring within the CIED RM team; 	Strong Positive Impact
<i>Criterion 3.1:</i> Impact on community in terms of health and safety	<ul style="list-style-type: none"> • The quality of the management of anticoagulants • The quality of care of some patients 	Moderate positive Impact

Table 5: Classification of Implicity RM platform impacts

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

According to its users, Implicity’s alert prioritization helps them to process critical alerts from all CIED manufacturers faster.

The latest Expert Consensus Statement on Practical Management of the Remote Device Clinic (Ferrick, Raj et al. 2023) insists on the fact that *“the definition of high-priority alerts, and of the response to them, is crucial for organization of care pathways, prioritization of review of alerts, and definition of acceptable response timelines”*. Agnostic platforms like Implicity RM platform enable by design alerts to be processed by order of priority, which prevents from interfering with the management of these priorities.

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.

According to its users, Implicity RM platform allows a quicker training of the new team members.

This directly illustrates one of the indicators mentioned for criterion 2.1: *“Time for acquisition of the skills or expertise associated with incorporating the Health Technology (HT) into practice”*. This result can be explained by the fact that healthcare professionals need to be trained on only one RM solution, rather than to train on five ones and that user respondents consider Implicity RM platform more intuitive than the manufacturers portals. Implicity today is the only platform able to aggregate CIED data coming from the five main CIED manufacturers in the French market (Rosier et al. 2016).

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

According to its users, Implicity RM platform allows a better tracking of RM activity. The possibility for its users to add notes, to archive comments (for event classification for example), or to download RM reports allows a better transfer of skills, knowledge and know-how within the CIED RM team.

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

Survey results showed that Implicity RM platform allowed:

- Time gain on processing critical alerts
- Easier identification of disconnected patient
- Time gain on managing disconnected patients
- Accelerated use or adoption of telemonitoring
- Time gain on billing management: Eight users respondents had no opinion on the statement *“Thanks to Implicity, I saved time on billing for remote monitoring (billing module, remote monitoring report management, etc.)”*. This high rate of “no opinion” can be explained by the fact that in several organizations, medical teams (that represent 95% of the user respondents of subgroup RM before) are not in charge of billing.
- Time gain on processing all patient alerts
- Better workload visibility
- Easier access to patient device history after they switched to a device from another manufacturer.

These results are reinforced by the free-text comments of the Subgroup RM Before ([Appendix 3](#)): *“Implicity provides a better overview of the workload and saves time”*; *“The time saved by Implicity is unquestionable”*; *“There are far fewer alerts on Implicity than on the manufacturer’s websites, which saves us a considerable amount of time!”*

These results address criterion 2.3 and directly answer several related indicators of HAS map: *Specific impacts for a patient/carer: time devoted to treatment follow-up, impacts on the ability to receive or treat patients.*

The latest Expert Consensus Statement on Practical Management of the Remote Device Clinic insists on the fact that *“Some of the issues identified by RM clinic stakeholders include managing differences unique to each CIED manufacturer (e.g., monitoring hardware, connectivity, programmability, nomenclature, accessibility, and web- based platforms) as well as the dynamic evolution and complexity of new devices and technology. There are other issues specific to the needs of individual RM clinics, which include the coordination of patient enrollment, scheduling, reporting, billing, and interfacing with electronic medical records.”* Implicitly, by allowing time gain, ease of billing management and ease of patient follow-up has a direct impact on the pain point described by the experts.

(Bawa, Kabra et al. 2023) emphasizes on the fact that *“the RM data obtained from the CIEDs poses a significant burden on the device clinics and providers who have to spend a sizable portion of their time and energy on triaging these data and identifying and responding to clinically relevant and actionable alerts”*. Modifying scheduling and planning capacities for health care services by helping CIED RM teams gain time and increase their visibility on their workload can alleviate this burden and have indirect positive impacts on improving their quality of life.

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

Users respondents agreed on the fact that Implicitly RM platform made the coordination of RM within the CIED RM team easier. This statement answers Criterion 2.4 indicator by easing the *“coordination between the stakeholders involved in the care process”*.

The Expert Consensus Statement on Practical Management of the Remote Device Clinic explains that *“critical to this organizational model is a team of CIED RM personnel with clearly defined roles—physicians and advanced allied professionals, nurses and/or cardiac physiologists, technicians, and administrative support staff”*. By easing coordination inside CIED RM teams, Implicitly directly addresses that point.

Considerations on criterion 2.5: Modifies stakeholders' working or living conditions.

(O'Shea et al. 2021) have highlighted the need for new management pathways for remote monitoring to alleviate clinical burden of healthcare professionals. The better coordination and RM task management that Implicitly RM platform allows together with the improvement in workload visibility according to the survey results, may also have a positive impact on working conditions, if ever alleviating the burden of CIED RM users.

Furthermore, the Expert Consensus Statement on Practical Management of the Remote Device Clinic emphasizes that the redistribution of administrative tasks can help alleviate burnout associated with such burdensome tasks.

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

Survey results have shown that Implicitly RM platform allowed:

- An improvement of the quality of care of some CIED RM patients
- A better management of patients with a potential indication for anticoagulants

(Bawa, Kabra et al. 2023) emphasizes that the data deluge adds significant burden and inefficiency to electrophysiology device clinics: the study showed that appropriate use of screening and stratification strategies (such as *“any rate-controlled AF recorded on a device in a patient who was already on oral*

anticoagulation") can effectively triage these data so that the device clinics are not overwhelmed and identify the urgent clinical alerts in a timely manner so that appropriate clinical interventions can be instituted.

b) Discussion on the survey results showing a non-significant p-value

Criterion 1.2: Modifies process pace or duration of the care process

Survey results could not lead to a conclusion on the impact of Implicity RM platform on the number of in person follow-ups per patients and per year compared to prior RM solution. The reduction in the number of in person follow-ups with RM has been demonstrated repeatedly in different studies, with a decrease in in person follow-ups of 45% and 56% in the TRUST (Varma, Epstein et al. 2010) and COMPAS (Mabo, Victor et al. 2012) studies, respectively; these decreases did not affect the rates of hospitalization or mortality.

For in person follow-up, international guidelines⁴ are as follows:

- ICD: Every year for RM patients vs every 6 months for non RM patients
- Pacemakers: Every 2 years for RM patients vs every year for non RM patients

By increasing RM adoption in France, Implicity might have an indirect impact on the number of in person follow-ups per patient per year globally.

Criterion 1.6: Modifies the quality and safety of the environment or context in which the process takes place

The majority of respondents answered "neutral" [9 to 11 depending on the manufacturer portal concerned] or "no opinion" [4 to 5 depending on the manufacturer portal concerned] to the question "Implicity is more secure than the manufacturer's portal".

Implicity has obtained the following certifications:

- ISO 13485 for operating a quality management system for following the scope design, manufacturing and sales of digital web platform for remote monitoring of patients in particular with cardiac diseases;
- ISO 27001 covering information, security management system for R&D, software development and maintenance, hosting, product management, customer support, clinical and regulatory affairs, business operations and internal IT;
- HDS for physical infrastructure hosting and Managed hosting.

The lack of significance of these results should therefore not be attributed to a negative difference in security level between Implicity and the manufacturers' portals, but rather to a lack of knowledge of security specificities of the Implicity platform from the CIED RM team.

c) Study limitations

This study has been performed in France and sent to 331 users of Implicity RM platform. Although the response rate (13.6%) can be considered as low, it is important to remind that a total of 41.3% (31/75) of the centers (Implicity customers) that received the survey had at least one respondent.

⁴ <https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Cardiac-Pacing-and-Cardiac-Resynchronization-Therapy> acceded June 30 2023

7. Conclusion

The objective of the present study was to evaluate the organizational impacts of Implicit RM platform on routine care practice compared to the use of manufacturers' portals (Carelink for Medtronic, Latitude for Boston Scientific, Merlin for Abbott, Home Monitoring for Biotronik, Smartview for MicroPort). This study seeks to demonstrate that Implicit RM platform has positive impacts on the following criteria 1.2, 1.3 ; 1.6; 2.1; 2.2 ; 2.3 ; 2.4 & 3.1. of the HAS map.

The present study failed to conclude on the organizational impacts of Implicit RM platform on the following criteria:

- **Criterion 1.2:** Modifies process pace or duration of the care process
- **Criterion 1.6:** Modifies the quality and safety of the environment or context in which the process takes place.

However, the study shows :

- **A moderate positive impact** on **Criterion 3.1:** Impact on community in terms of health and safety
- **A strong positive impact** of Implicit RM platform on the statements related to the following criteria of HAS MAP.
 - **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 2.4:** Modifies scheduling and planning capabilities between care structures or combinations of stakeholders

These positive results regarding Implicit RM platform corroborate the recent expert consensus statement released by HRS/EHRA/APHRS/LAHRS during this year's annual Heart Rhythm Scientific Congress in New Orleans on the "Practical Management of the Remote Device Clinic" 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 on officially recommended as a standard of care by the international CIED RM expert community.

8. References

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9. Appendices

Appendix 1: French to English translation of the questionnaire sent to Implicity RM platform users.

PART 1

French questions asked to healthcare professionals	English translation
Quelle est votre adresse email ?	What is your email address?
Quelle est votre fonction (médecin, infirmier(e), autre) ?	What is your function (Practitioner, Nurse, other)?
Le centre dans lequel vous effectuez la télésurveillance des patients porteurs de prothèses est : (un CHU, un CH, un ESPIC, un Etablissement privé). ? [1]	The center in which you remotely monitor your patients with cardiac Implant electronic Device (CIED) is: (un CHU, un CH, un ESPIC, un Etablissement privé)?
Depuis combien de temps utilisez-vous la plateforme Implicity (moins de 3 mois, entre 3 mois et 1 an, plus d'un an) ?	How long have you been using Implicity (less than 3 month, between 3 month and 1 year, more than a year)?
Quel est le nombre de patients implantés actuellement télésurveillés pour leur prothèse dans votre centre ?	How many CIED patients are currently remotely monitored in your center?
Cochez les marques de prothèses que vous télé suivez (Medtronic, BostonScientific, Abbott/ St Jude, Biotronik, Microport/Livanova/Sorin)	Check all the manufacturers of the cardiac implants you are currently remotely monitoring. (Medtronic, BostonScientific, Abbott/ St Jude, Biotronik, Microport/Livanova/Sorin)
Réalisez-vous la télésurveillance des patients implantés de prothèses avant d'utiliser la plateforme Implicity ?	Did you remotely monitor CIED patients before you started using Implicity?
Avant d'utiliser la plateforme Implicity, utilisiez-vous d'autres outils que les portails des fabricants de prothèses pour la télésurveillance de vos patients (autres plateformes agnostiques, logiciels ou outils de bureautique complémentaires, etc.) ?	Before you started using Implicity, did you use any other tool to monitor your CIED patients, other than the manufacturers' software (other agnostic platforms, complementary software or office tools, etc.)?
Lesquels ?	Which ones?

PART 2

Depuis que j'utilise la plateforme Implicity, je traite plus vite les alertes critiques, toutes marques confondues, grâce aux fonctionnalités de priorisation des alertes	Implicity's alert prioritization helps me to process critical alerts from all CIED manufacturers faster.
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à Carelink [Medtronic]	My remote monitoring activity is better tracked on Implicity than on Carelink [Medtronic].
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à Latitude [Boston Scientific]	My remote monitoring activity is better tracked on Implicity than on Carelink [Boston Scientific].
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à Merlin [Abbott]	My remote monitoring activity is better tracked on Implicity than on Merlin [Abbott]
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à Home Monitoring [Biotronik]	My remote monitoring activity is better tracked on Implicity than on Home Monitoring [Biotronik]
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à Smartview [Microport]	My remote monitoring activity is better tracked on Implicity than on Smartview [Microport]
La plateforme Implicity me permet d'avoir une meilleure traçabilité de mon activité de télésurveillance par rapport à mon ancienne plateforme agnostique le cas échéant	My remote monitoring activity is better tracked on Implicity than on my previous agnostic platform if applicable
Depuis que j'utilise la plateforme Implicity, l'accès à l'historique des données de la prothèse en cas de changement de marque de boîtier est amélioré	Thanks to Implicity, it's easier to access my patient's device history, even after they switched to a different device manufacturer.
Depuis que j'utilise la plateforme Implicity, la qualité de prise en charge de certains de mes patients sous télésurveillance est améliorée	Thanks to Implicity, the quality of care of some of my remotely monitored patients has improved
Depuis que j'utilise la plateforme Implicity, les patients avec une indication potentielle d'anticoagulants sont mieux gérés (en cas de fibrillation atriale par exemple)	Thanks to Implicity, patients with a potential indication for anticoagulants are better managed (e.g., for patients with atrial fibrillation))
Depuis que j'utilise la plateforme Implicity, j'identifie plus facilement les patients déconnectés	Thanks to Implicity, I am able to identify disconnected patients more easily
Depuis que j'utilise la plateforme Implicity, je gagne du temps sur la gestion des patients déconnectés grâce à la fonctionnalité d'envoi de SMS.	Thanks to Implicity, I save time managing disconnected patients with the SMS functionality.

Depuis que j'utilise la plateforme Implicity, je suis plus de patients en télésurveillance et plus vite (usage ou adoption accélérée de la télésurveillance)	Thanks to Implicity, I monitor more patients faster (accelerated use or adoption of telemonitoring).
Depuis que j'utilise la plateforme Implicity, je traite plus rapidement l'ensemble des alertes	Thanks to Implicity, I am able to process all the alerts faster
Depuis que j'utilise la plateforme Implicity, je gagne du temps pour facturer la télésurveillance (module de facturation, gestion de rapports de télésurveillance, etc.)	Thanks to Implicity, I saved time on billing for remote monitoring (billing module, remote monitoring report management, etc.):
Depuis que j'utilise la plateforme Implicity, j'ai une meilleure visibilité sur ma charge de travail	Thanks to Implicity, I have better visibility of my workload
Depuis que j'utilise la plateforme Implicity, j'ai constaté une baisse du nombre de consultations par patient et par an	Thanks to Implicity, I notice a decrease in the number of in person follow-ups per patient per year.
Par rapport à mon ancien moyen de télésurveillance, la plateforme Implicity est plus intuitive	Compared to my previous remote monitoring system, Implicity is more intuitive
Depuis que j'utilise la plateforme Implicity, la coordination de la télésurveillance au sein de l'équipe de rythmologie est facilitée	Thanks to Implicity, the coordination of remote monitoring within the CIED RM team becomes easier.
Depuis que j'utilise la plateforme Implicity, l'équipe de télécardiologie ou les nouveaux membres de l'équipe sont formés plus rapidement	Thanks to Implicity, the telecardiology team or new team members are trained more quickly
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à Carelink [Medtronic]	Implicity is more secure (user authentication, access management, etc.) than Carelink [Medtronic].
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à Latitude [Boston Scientific]	Implicity is more secure (user authentication, access management, etc.) than Latitude [Boston Scientific].
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à Merlin [Abbott]	Implicity is more secure (user authentication, access management, etc.) than Merlin [Abbott].
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à Home Monitoring [Biotronik]	Implicity is more secure (user authentication, access management, etc.) than Home Monitoring [Biotronik].
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à Smartview [Microport]	Implicity is more secure (user authentication, access management, etc.) than Smartview [Microport]
La plateforme Implicity est plus sécurisée (authentification des usagers, gestion des accès etc.) par rapport à mon ancienne plateforme agnostique le cas échéant	Implicity is more secure (user authentication, access management, etc.) than my previous agnostic platform if applicable.
Commentez votre réponse à la question précédente en expliquant pourquoi ?	Comment on your answer to the previous question and explain why.

Avez-vous des commentaires additionnels sur les impacts de l'usage de la plateforme Implicity sur votre pratique ?	Do you have any additional comments on the impacts of the use of Implicity on your practice?
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Appendix 2: Detailed table of users' answers

	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>No Opinion</i>
Implicity's alert prioritization helps me to process critical alerts from all CIED manufacturers faster.	0	2	2	7	8	1
My remote monitoring activity is better tracked on Implicity than on Carelink [Medtronic].	0	0	2	7	10	1
My remote monitoring activity is better tracked on Implicity than on Carelink [Boston Scientific].	0	0	2	8	8	2
My remote monitoring activity is better tracked on Implicity than on Merlin [Abbott]	0	0	2	7	10	1
My remote monitoring activity is better tracked on Implicity than on Home Monitoring [Biotronik]	0	1	2	7	8	2
My remote monitoring activity is better tracked on Implicity than on Smartview [Microport]	0	0	2	5	11	2
My remote monitoring activity is better tracked on Implicity than on my previous agnostic platform if applicable	0	0	1	1	3	15
Thanks to Implicity, it's easier to access my patient's device history, even after they switched to a different device manufacturer.	0	0	4	8	5	3
Thanks to Implicity, the quality of care of some of my remotely monitored patients has improved	1	0	4	7	7	1
Thanks to Implicity, patients with a potential indication for anticoagulants are better managed (e.g., for patients with atrial fibrillation))	0	1	6	8	5	0
Thanks to Implicity, I am able to identify disconnected patients more easily	0	1	3	7	9	0
Thanks to Implicity, I save time managing disconnected patients with the SMS functionality.	0	1	1	6	4	8
Thanks to Implicity, I monitor more patients faster (accelerated use or adoption of telemonitoring).	1	2	2	7	8	0
Thanks to Implicity, I am able to process all the alerts faster	0	2	1	8	9	0
Thanks to Implicity, I saved time on billing for remote monitoring (billing module, remote monitoring report management, etc.):	0	2	1	1	8	8

	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>No Opinion</i>
Thanks to Implicity, I have better visibility of my workload	0	2	2	4	10	2
Thanks to Implicity, I notice a decrease in the number of in person follow-ups per patient per year.	2	4	6	3	1	4
Compared to my previous remote monitoring system, Implicity is more intuitive	0	0	1	6	8	5
Thanks to Implicity, the coordination of remote monitoring within the CIED RM team becomes easier.	0	0	3	9	6	2
Thanks to Implicity, the telecardiology team or new team members are trained more quickly	0	0	6	5	3	6
Implicity is more secure (user authentication, access management, etc.) than Carelink [Medtronic].	2	0	10	3	1	4
Implicity is more secure (user authentication, access management, etc.) than Latitude [Boston Scientific].	1	0	10	3	1	5
Implicity is more secure (user authentication, access management, etc.) than Merlin [Abbott].	2	1	11	1	1	4
Implicity is more secure (user authentication, access management, etc.) than Home Monitoring [Biotronik].	1	0	11	2	1	5
Implicity is more secure (user authentication, access management, etc.) than Smartview [Microport]	2	1	9	3	1	4
Implicity is more secure (user authentication, access management, etc.) than my previous agnostic platform if applicable.	1	0	5	1	1	12

Appendix 3: free comments of the respondent of Subgroup RM BEFORE:

User respondent	Center respondent	Comment in French	English translation
Physician	Private Practice	outils originaux tels l'algorithme de reclassification des tracés des enregistreurs ECG implantables	original tools such as the algorithm for reclassifying the signals of implantable ECG recorders
Physician	Private Practice	je pourrais difficilement m'en passer	I could hardly do without it
Nurse	CH	Malgré certains problèmes liés à la remontée d'informations des constructeurs, Implicity permet d'avoir un meilleur visuel sur la charge de travail et aussi de gagner du temps de part son ergonomie bien faite et regroupant toutes	Despite some problems linked to the transfer of information from manufacturers, Implicity provides a better overview of the workload, and saves time thanks to its well-designed ergonomics, covering all brands of prosthesis.

		les marques de prothèses	
Nurse	CHU	Devant l'essor de la télésurveillance des prothèses cardiaques le gain de temps apporté par implicit est indiscutable et la réactivité suite à nos suggestions est très appréciée et toujours en évolution grâce à une équipe dynamique et disponible aussi des nouvelles propositions sont déjà prêtes à être soumises pour améliorer et personnaliser la prise en charge des patients	With the boom in remote monitoring of CIEDs, the time saved by implicit is unquestionable, and the responsiveness to our suggestions is much appreciated and constantly evolving, thanks to a dynamic and available team. New proposals are already ready to be submitted to improve and personalize patient care.
Nurse	CHU	Implicit nous permet facilement d'évaluer nos pratiques, de faire des stats de groupes de patients. Elle nous permet aussi de gérer de façon plus fine les réglages d'alertes. Les alertes sont donc bien moins nombreuses sur Implicit que sur les sites fabricants, ce qui nous fait gagner un temps non négligeable! La gestion des sondes est facilitée aussi avec la possibilité de choisir le délai dans les graphes.	Implicit makes it easy for us to evaluate our practices and to produce statistics for groups of patients. It also enables us to manage alert settings more finely. There are far fewer alerts on Implicit than on the manufacturer's websites, which saves us a considerable amount of time! Probe management is also facilitated by the ability to choose the delay in the graphs.
Nurse	CHU	Les mises à jour fréquentes sont un plus (améliorations de la plateforme) un moins (bugg du site, donnés tracées effacés).	Frequent updates are a plus (platform improvements) and a minus (site bugs, tracked data deleted).