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The cost of implementing shared decision-making in medication adherence: evidence from the IMA-RCT study

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Abstract

Background

The Initial Medication Adherence (IMA) intervention is a shared decision-making intervention designed to improve both medication adherence and clinical outcomes in patients with cardiovascular disease and/or diabetes. Uncertainty regarding implementation costs may hinder the adoption of an efficient intervention. The study aim is to describe the costs of implementing the IMA intervention.

Methods

The IMA intervention was implemented in 12 Primary Care (PC) centres in Catalonia (Spain) between 2021 and 2022. A cost of implementation study based on the Stages of Implementation Completion framework was performed using the Cost of Implementing New Strategies tool. Material and human resources were recorded for each activity undertaken within each stage and phase of implementation and subsequently converted into monetary cost. Human resources included the time contributed by healthcare managers, general practitioners, nurses and implementation technicians. All costs were classified as fixed or variable, and as one-time or time-dependent. The pre-implementation and implementation phases spanned one year. Efforts during the sustainability phase were projected for an additional five year period based on expert judgement. Costs were extrapolated to a scenario involving 100 PC centres using fixed and variable costs estimates.

Results

The total cost of implementing and sustaining the IMA intervention over five years in 12 PC centres was €48,285, whereas the estimated total cost per 100 PC centres was €132,631. The phase with the largest proportion of costs was the pre-implementation phase. Human resource costs exceeded material costs. During the pre-implementation and implementation phases, most human resources were undertaken by technicians, whereas healthcare professionals accounted for the majority of costs during the sustainability phase. C Costs were highest in the first year, when the pre-implementation and implementation phases took place. During the sustainability phase, costs peaked in the fourth year.

Conclusions

Implementing the IMA intervention appears to be affordable. For a low-intensity intervention that requires minimal material resources, effective planning is the determinant of a successful implementation. Detailed information on implementation costs can support decision-making in both the original and other settings by facilitating context-specific adaptation.

Trial registration

ClinicalTrials.gov, NCT05026775. Registration date 23082021.

Contributions to the literature

- Detailed implementation cost information can support decision-making across settings by enabling context-specific adaptation.
- The classification of costs as fixed or variable, and as time-dependent or one-time, enabled the extrapolation of intervention implementation costs from 12 to 100 primary care centres.
- Implementing a shared decision-making intervention across multiple primary care centres to improve medication adherence and clinical outcomes appears to be affordable.

Introduction

Health economics is a cornerstone of health technology assessment, particularly cost and cost-effectiveness studies, focusing on the impact and efficiency of interventions. In this context, several implementation frameworks, such as Proctor's (1) or the Consolidated Framework for Implementation Research (2,3), highlight the importance of estimating implementation costs, which are affected by the context, the intervention, and the implementation strategy used (4). However, the cost of implementation analyses remain uncommon, even in studies following implementation frameworks (5,6).

Cost of implementation analyses evaluate the costs of translating an intervention into practice (7), offering a highly valuable piece of information for decision-makers by taking into account the specific context in which the intervention is to be implemented (8). Uncertainty regarding implementation costs may hinder the adoption of an efficient intervention or lead to the adoption of an intervention that ultimately proves to be unsustainable (9).

Stages of Implementation Completion (SIC) framework

Standardising the recording of costs for cost of implementation analyses is challenging (7). To facilitate extrapolation to diverse contexts, cost of implementation analysis should be transparent and flexible, clearly distinguishing between fixed, variable, and time-dependent costs. The SIC framework tracks the activities performed to achieve the key implementation milestones of an intervention (10) across three phases, pre-implementation, implementation and sustainability, which comprimse eight stages.

- The *pre-implementation* phase–comprising the *'Engagement'*, *'Consideration of feasibility'* and *'Readiness Planning'* stages–includes all activities related to exploration and intervention adoption or preparation (11).
- The *Implementation* phase –comprising the *'Staff hired and trained'*, *'Fidelity monitoring'*, *'Services and consultation begin'*, and *'Ongoing services, consultation, fidelity monitoring and feedback'* stages–

covers all activities related to an active intervention implementation. These activities could be system, clinician or user related.

- The *Sustainability*, a single-stage–*'Competence'*–phase, involves all activities that support the continued long-term use of the intervention in practice (11).

The Cost of Implementing New Strategies (COINS) tool (12) was developed to consistently and transparently record the specific material and human resources associated with each stage.

Although shared decision-making (SDM) is an ethical imperative that contributes to the development of a more advanced and patient-centred healthcare system, its implementation is not yet widespread, partly due to limited evidence on its health benefits and the effectiveness of strategies designed to promote it. The Initial Medication Adherence (IMA) intervention is an SDM-based intervention designed to improve both adherence to medications for cardiovascular disease and diabetes prescribed in primary care (PC), and patients' clinical outcomes. An effectiveness-implementation hybrid study was conducted, incorporating both a cost-effectiveness evaluation and a cost of implementation analysis. The IMA intervention enhanced the experiences of both patients and healthcare professionals (13). Patients felt actively engaged and valued the clear information they received, while professionals appreciated the SDM training and decision aids. They also demosntrated increased knowledge and more positive attitudes towards SDM. Notably, nurses played a key role in the mangement of patients with chronic conditions in PC, given their proximity to patients and their potential to promote SDM and patient autonomy. Nevertheless, contextual barriers such as time constraints and high workload limited implementation (13). Although the intervention had no impact on medication adherence, it was associated with potential benefits in terms of blood pressure reduction were observed (14) and represented good value-for-money (15).

Methods

The aim of this study is to provide a detailed description of the costs of implementing the IMA intervention, broken down by phase and stage.

A cost of implementation study was developed within the IMA-cRCT study (NCT05026775), a multicentre pragmatic cluster RCT (24 PC centres, more than 300 professionals, and more than 3,000 patients), that evaluated a complex, patient-centred intervention to improve medication adherence to treatments for cardiovascular disease and diabetes. This study was conducted considering the perspective of institution where the intervention is implemented. The IMA intervention was implemented in 12 PC centres and 39 of their corresponding community pharmacies in Catalonia (Spain).

Setting

The Spanish National Health System (NHS) is tax-funded and guarantees universal coverage free at the point of care, with some exceptions, such as prescription medications, which are dispensed through

community pharmacies. The NHS is mainly administered by Spanish regions; in Catalonia, it is managed by the Catalan Health Service. Health delivery is based on PC, where chronic conditions are managed. The Catalan Health Institute (ICS) manages 80% of the public PC centres in Catalonia. This institution is organised into supraterritorial units, called DAP (Primary Care Directorates), which are subdivided into units with a smaller territorial scope, called SAP (Primary Care Service), and these, subsequently, into PC centres.

PC centres are staffed by multidisciplinary teams, including General Practitioners (GPs) and nurses, while community pharmacies are privately owned but operate under public regulation and are integrated into the NHS. The medications considered in the IMA intervention can only be obtained from community pharmacies after a GP prescription. Community pharmacists are represented by the four provincial Official Colleges of Pharmacists. These Colleges are professional regulatory bodies responsible for ensuring professional standards and ethics, supporting continuing education, and overseeing professional practice in the public interest. They also provide legal and technical guidance and collaborate with health authorities to ptomote pharmaceutical care and public health initiatives.

The IMA intervention and its implementation process

The IMA intervention promotes SDM between patients and healthcare professionals while supporting the standardisation of clinical practice among all PC professionals involved in the patient's care (GPs, nurses and pharmacists) to improve both initiation and long-term adherence to pharmacological treatments. For this study, only implementation-related activities were considered. Three key implementation strategies—professional engagement, SDM training for professionals, and the use of patient decision aids (leaflets and a website)—were used to support the core processes of the intervention.

Pre-implementation phase: January 2021–February 2022

The key managers of participating institutions, ICS and the four Official Colleges of Pharmacists, were contacted and informed about the project. Subsequently, managers of DAP and SAP were contacted, followed by the managers of PC centres and community pharmacies where the IMA intervention would be introduced. During these meetings, the project was presented and the importance of SDM was emphasised, along with the need to use evidence-based implementation strategies and to generated data on the intervention's impact.

In parallel, two key components were developed through of a review of the available literature and clinical practice guidelines and based on previous results from the qualitative and pilot studies (16–18): decision aids and training for professionals. The decision aids (leaflets and website) were designed by a graphic designer to support both patients and professionals by guiding discussions about the disease and available treatments, encouraging patient participation, and helping to standardise practice across

GPs, nurses and pharmacists. These decision aids were validated by patients. The shared training programme was designed with the support of an expert on SDM training. The programme provided professionals with both knowledge and skills needed to apply SDM. It covered the understanding and standardisation of the prescription process, the principles and practice of SDM, and communication skills using the decision aids. Detailed information is provided elsewhere (13,14).

Finally, a monitoring plan for intervention implementation was designed to establish a communication circuit between PC professionals and the research team.

Implementation phase: March 2022–September 2022

First, an expert in SMD training trained the trainers (two GPs and two nurses). These trainers subsequently delivered the training to participating professionals in two three-hour sessions at each PC centre. Then, printed and digital decision aids and the web link were distributed to the PC centres and community pharmacies.

Among the participating GPs and nurses, one professional from each PC centre was designated as the implementation coordinator. A communication circuit, with the implementation coordinator as the main contact person, was established to maintain contact with the PC centres and community pharmacies and address any issues that arose during the implementation. The coordinator's responsibilities included collecting information from other professionals about the implementation of the intervetnion in their PC centre and communicating this information to the research team through monthly phone calls.

Sustainability

Sustainability is considered any effort needed to sustain the key components of the intervention implementation strategy, namely interdisciplinary SDM training, updated decision aids, and monitoring. These efforts were estimated with the support of stakeholders from the participating organisation: PC managers and professionals from the 'talent' unit, responsible for training programs and the implementation of innovations.

Data collection

Pre-implementation and implementation phase

The implementation team systematically documented the costs incurred during the pre-implementation and implementation phases following the COINS approach (12). For each activity undertaken within the stages one to seven of the SIC framework, the team registered (10) both *human resources*—the amount of staff time devoted to each activity, stratified by professional (healthcare manager, GP, nurse, and

implementation team, i.e., junior and senior technician)—and *material resources*—the type and number of material resources required.

Sustainability

For sustainability, meetings were held with PC managers and professionals from the ICS talent-unit experts. Through presentations, the stakeholders became familiar with both the intervention and its key components, and the implementation strategies. They were also introduced to the SIC framework and COINS tool.

Based on their expert judgement, they helped identify, for each intervention component and implementation activity, the efforts required to ensure long-term sustainability, indicating the expected frequency and intensity. During the sustainability phase, the potential for institutionalising the intervention to streamline or reduce certain costs over time was also considered. However, to avoid underestimating long-term resource needs, we adopted a deliberately conservative approach and maintained the same intensity of implementing activities as the used during the pre-implementation and implementation phases. This ensured that the sustainability estimates reflected a conservative upper-bound scenario. After a structured, component-by-component discussion, the research team synthesised a five-year implementation plan, representing the minimum time horizon needed to capture the recurrence of sustainability actions. The experts reviewed the proposal and final sustainability efforts were defined.

Some of the efforts undertaken by the implementation team were related to the process evaluation of the IMA-cRCT study and may therefore have overestimated the implementation efforts. Therefore, the implementation team estimated a reproduction rate for each cost, indicating the proportion of the each effort that would actually be required in a non-research context.

Monetary costs

The ICS finance department facilitated information on the average salary for 2023 for all professional groups (healthcare manager, GP, nurse, and the implementation team). For each professional category, the effective annual working hours were estimated by multiplying weekly working hours by the number of weeks worked per year, excluding training days and annual leave. The annual salary was then divided by the number of effective working hours to calculate the hourly cost (Table 1). Material costs were obtained directly from invoices.

Table 1
Hourly cost by professional category (€, 2023).

Professional Category	Hourly cost (€, 2023)
Healthcare manager	50.53
General Practitioner	35.44
Nurse	24.96
Senior technician	25.24
Junior technician	20.57

Data analysis

Cost classification

After being collected, costs were classified according to their behaviour in relation to the scale of implementation as fixed or variable costs. *Fixed costs* were defined as those that remain constant regardless of the level or intensity of implementation activity. In this study, these included upfront investments such as the development and graphic design of decision aids (leaflets and website), the design of the SDM training programme, and the initial setup of the web platform. In contrast, *variable costs* were those that changed in proportion to the volume or reach of implementation activities. Examples included the number of training sessions delivered according to the number of PC centres involved, professionals' time spent attending training, and the production of printed decision aids.

Costs were also classified according to their temporal occurrence as one-time (non-recurring) or time-dependent (recurring) costs. *One-time costs* referred to those incurred only once during the implementation process, such as the initial adaptation of the intervention to the local context, the first delivery of SDM training sessions, or the initial configuration of the monitoring systems. *Time-dependent costs* referred to those incurred repeatedly over time to sustain the intervention. These included refresher training sessions for new or existing professionals, ongoing coordination and monitoring activities (e.g., monthly communication between implementation coordinators and the research team), periodic updates of decision aids to reflect new evidence, and maintenance of the website and other supporting tools.

Cost calculations

We calculated the cost of each activity by multiplying the number of hours spent by each professional by the estimated hourly cost (human resource costs) and adding the corresponding material costs. Total and phase-specific costs were then estimated by summing all activity-level costs, adjusted by the

reproduction rate. For time-dependent costs incurred during the sustainability phase costs were projected according to their expected frequency, based on the estimated recurrence.

Scenarios for total cost calculation

The main scenario estimated costs of implementation for the 12 PC centres where the IMA intervention was implemented. However, given its potential for wider implementation, a second scenario was analyzed, in which the cost of implementing the intervention was extrapolated to 100 PC centres, taking into account fixed and variable costs.

The time spent by healthcare professionals attending the training (6 hours per trained professional) and monitoring the intervention implementation (3.5 hours per PC centre) was not considered, as this time was already incorporated into their weekly schedules as training time. However, a sensitivity analysis was conducted in which these costs were included.

Results

The total cost of implementing and sustaining for 5 years the IMA intervention in the 12 PC and 37 community pharmacies where it was implemented was €48,285 (i.e. €4,024 per PC assuming that community pharmacies are evenly distributed among PC centres), while the total cost per 100 PC centres was €132,631.

Figure 1 shows the total number of hours (a) and costs (b) for each type of professional and phase and the relative weight in % (c, d). Most of the efforts made during the pre-implementation and implementation phases were made by technicians (57%) and practising healthcare professionals (40%), with only 3% of total time devoted by managers. Pre-implementation stages showed a more balanced distribution of hours across roles, while implementation stages showed greater efforts from technicians, except *Staff Hired and Trained* stage.

In terms of cost, *Readiness Planning* and *Consideration of Feasibility* were also the stages with the highest costs (€20,976€ and €5,292). However, the difference between them was higher than in terms of hours invested due to relevant material costs (representing 38% of the stage costs) in the *Readiness Planning* stage. *Staff Hired and Trained* shows a similar cost to *Consideration of Feasibility*, due to a higher proportion of hours invested by healthcare professional roles.

Figure 2 shows the weight of each phase (left) and stage (only considering pre-implementation and implementation stages) in the total implementation cost in 12 PC centres (a) and in 100 PC centres (b).

Pre-implementation accounted for the largest proportion of total costs in both scenarios; however, its relative share decreased from 55% for 12 participating PC centres to 46% when extrapolated to 100 centres. In contrast, as the number of centres increased, the share of implementation-phase costs rose

(from 15% to 22%). The share of sustainability-phase costs remained relatively stable at around one third of total costs, regardless of the number of PC centres.

Figure 3a shows the annual costs over the first 6 years for 12 PC centres. Costs related to the pre-implementation and implementation phase are concentrated in the first year, whereas costs incurred between years 2 to 6 reflect the frequency of activities associated with the sustainability phase. Apart from the first year (slightly higher than €35,000), the highest cost is observed in the fourth year, reaching nearly €15,000 (of which over €5,000 is attributable to healthcare professional time and around €5,000 to material resources). The remaining years have annual costs below €5,000.

Figure 3b presents the extrapolated annual cost for 100 PC centres. Costs in the first year exceed €90,000. The next highest cost is observed in the fourth year, at approximately €40,000, while costs in the second and sixth years were around €10,000. In these years, the largest share of costs is attributable to healthcare professionals. Costs in the third and fifth years were close to zero.

DISCUSSION

Health policy decision-making must be based on the best available evidence. In this regard, we present the cost of implementing an SDM-based intervention to improve medication initiation in 12 PC centres in Catalonia (Spain). The total cost of implementing the intervention was €33,723, while the cost of sustaining it for five years after the first year of implementation was €14,562.

Results suggest that implementing the IMA intervention could be affordable, as considering that the intervention was delivered to 2,148 patients, the implementation cost per patient (€16) well below the threshold reported in the literature as the maximum acceptable cost of an intervention aimed at improving medication adherence (19). The highest implementation cost occurs in the first year, while sustaining the intervention requires substantially fewer resources, both in terms of personnel and materials. Furthermore, when extrapolating the intervention to 100 PC centres, costs associated with healthcare professionals increased proportionally more than those related to healthcare technicians or consumable materials. This is because variable activities rely primarily on healthcare professionals, whereas fixed activities depend more on healthcare technicians. Additionally, once the intervention is embedded within the organisation's culture and is integrated into routine practice, the cost of sustaining its implementation would likely decrease or even disappear, as it would be maintained through existing structures and professional routines (20,21).

During the first year, the main cost drivers are concentrated in the pre-implementation phase, particularly in *Readiness Planning*. In a low-intensity intervention that does not require substantial material resources, the key determinant of success is effective planning. Investing time and resources at this stage facilitates the implementation and supports long-term sustainability of the intervention.

The cost of the intervention in 100 PC centres is three times higher than in 12 PC centres, despite the number of centres increasing eightfold. This is because significant fixed costs, particularly those

incurred in the pre-implementation phase, become proportionally less important as more centres are involved. An exception to this pattern is observed *Staff Hired and Trained*, where variable costs predominate. Consequently, this stage accounts for a greater relative proportion of the total cost when extrapolating to 100 PC centres than when implementing the intervention in 12 PC centres.

This estimation was performed taking into account the three components determining the cost of implementation detailed by Proctor (4). The first is the intervention complexity, which remains the same regardless of the number of centres in which it is implemented. The second is the context complexity. Given that the intervention was implemented in the trial across 12 PC centres with diverse characteristics distributed throughout the entire territory (22), we would not have expected significant changes in the implementation due to contextual factors beyond those already considered. However, the third component, the implementation strategy, could substantially influence the estimated implementation costs. The rationale for this estimation was to project the implementation of the intervention in 100 PC centres; however, this number of centres would require a scale-up strategy, which would be less resource-demanding per centre (23,24).

It is important to highlight that we did not consider the time invested by trained professionals in the training sessions, as healthcare professionals have protected time for training in their daily schedules. Should this cost be considered, the cost of the *Staff Hired and Trained* stage should be increased by 23,556.88€ (59 GPs, 41 nurses and 39 community pharmacists, each investing 6 hours at their respective unit costs) and the costs of the *Ongoing services, consultation, fidelity, monitoring and feedback* stage by €3,886.54 (12 implementation coordinators, 10 GP and 2 nurses, 1 hour per month of intervention), and similar estimations should be applied to those activities that require receiving training, such as refresher training or training of new professionals in the sustainability phase. Conversely, we did consider the time invested by trainers, not only in the training session itself but also in transportation.

Capturing all costs involved in the implementation process is difficult, however, a detailed monitoring process such as the one followed in this study can help decision makers (8,25). This information should be accompanied by other relevant data, such as the cost-effectiveness analyses in the short and long-term.

Implementation costs are highly context-dependent. In this regard, offering a transparent and detailed information registry could support decision makers across different contexts with varying characteristics, such as greater geographic dispersion, different professional costs, or different technological equipment, when deciding whether to adapt and implement an intervention.

Strengths and limitations

This study presents an implementation cost analysis conducted alongside a large-scale trial, representing a novel approach. Moreover, it provides valuable insights into the costs of implementing a patient-centred intervention based on SDM in PC.

Although the study was conducted within the framework of a research project, the working conditions reflected real-life practice. To avoid the overestimation of resources derived from the research project and to remain as close as possible to real-world conditions, a reproduction rate was applied. However, in real practice, research and implementation activities could overlap, making it difficult to precisely attribute costs exclusively to the implementation phase. Another limitation of this study is that we were unable to track the time invested by professionals in applying SDM during patient consultations. However, we assumed that this intervention is delivered as part of routine practice with a slight increase in consultation time, which is expected to be offset in subsequent encounters, as indicated by the participating professionals (26). Lastly, cost estimates for the sustainability phase were partly based on assumptions and extrapolations rather than on direct measurements, which may affect the precision of the estimated costs. However, these assumptions were theoretically grounded and developed through extensive discussions with teams from the healthcare system.

CONCLUSIONS

The implementation of the IMA intervention appears to be affordable in a PC setting such as the one in which the intervention was implemented, with marginal costs per centre expected to decrease as the number of centres adopting the intervention increases. Providing a detailed breakdown of the implementation costs can support decision-making both in the original implementation context and in other settings, as this level of detail enables contextual adaptation.

Declarations

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Author Contribution

IAL and MRV contributed to the conception and design of the work; ASV and CCP participated in the acquisition of data, IAL, MRV and CCP contributed in the analysis of data. All authors contributed to the interpretation of data. IAL, MRV and CCP have drafted the work and MGG, ASV, MTPM, MCOP and MNN have haver substantively reviewed it.

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Data Availability

All data supporting the findings of this study are available within the paper and its Supplementary Information.

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Figures

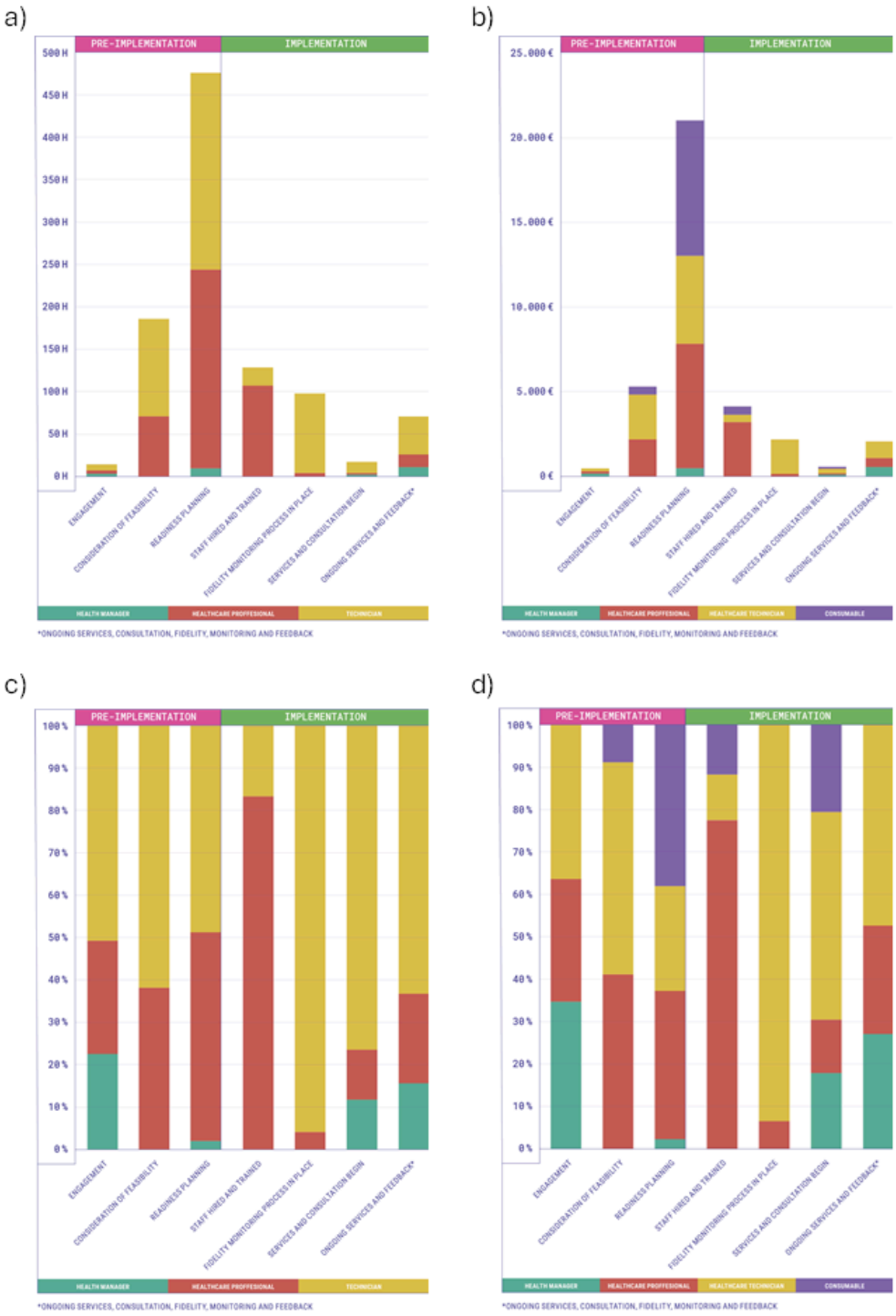


Figure 1

Time (a, c) and cost (b,d) per stage in the pre-implementation and implementation phase by professional role, expressed in absolute (a,b) and relative terms (c,d).

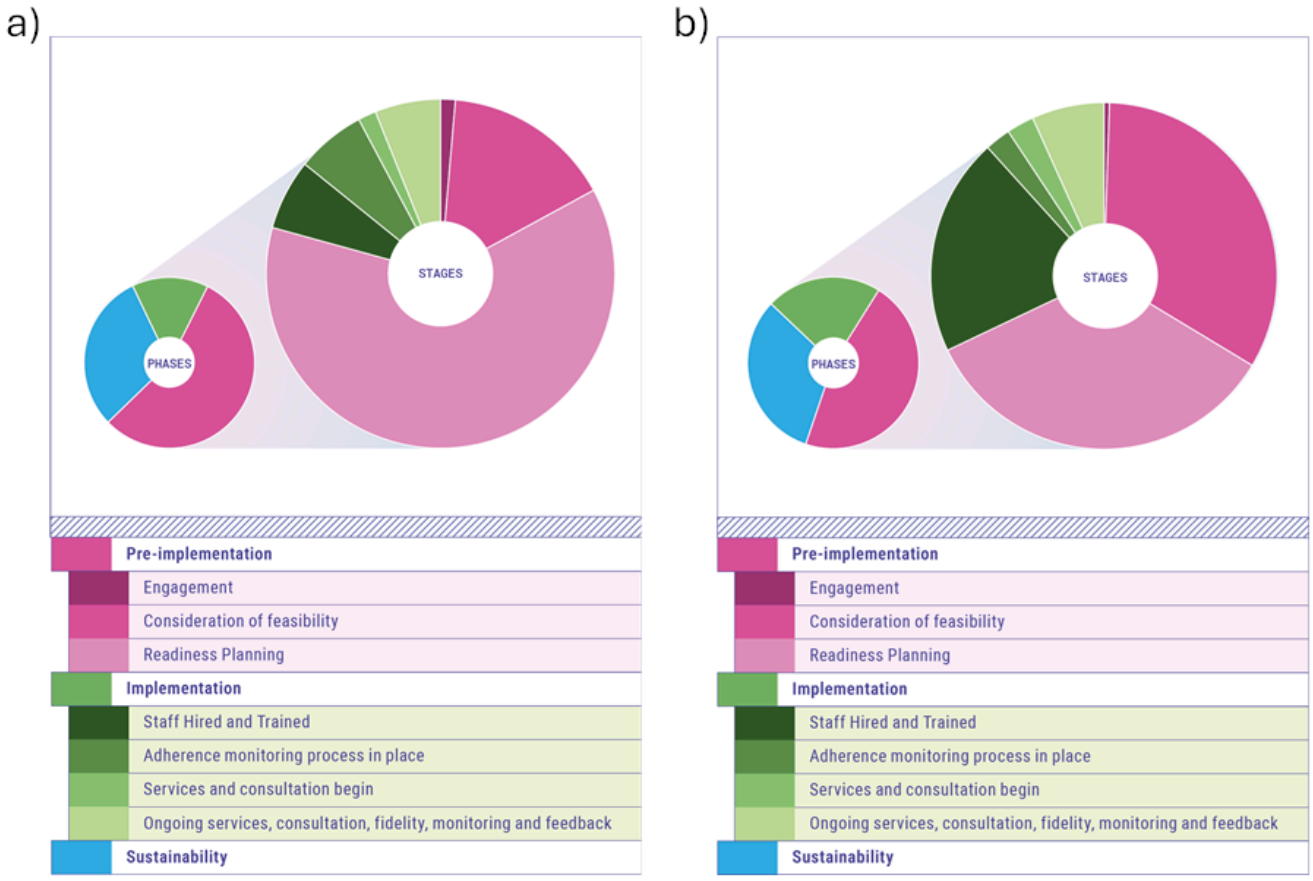


Figure 2

Total cost by stage in 12 (a) and 100 (b) PC centres.

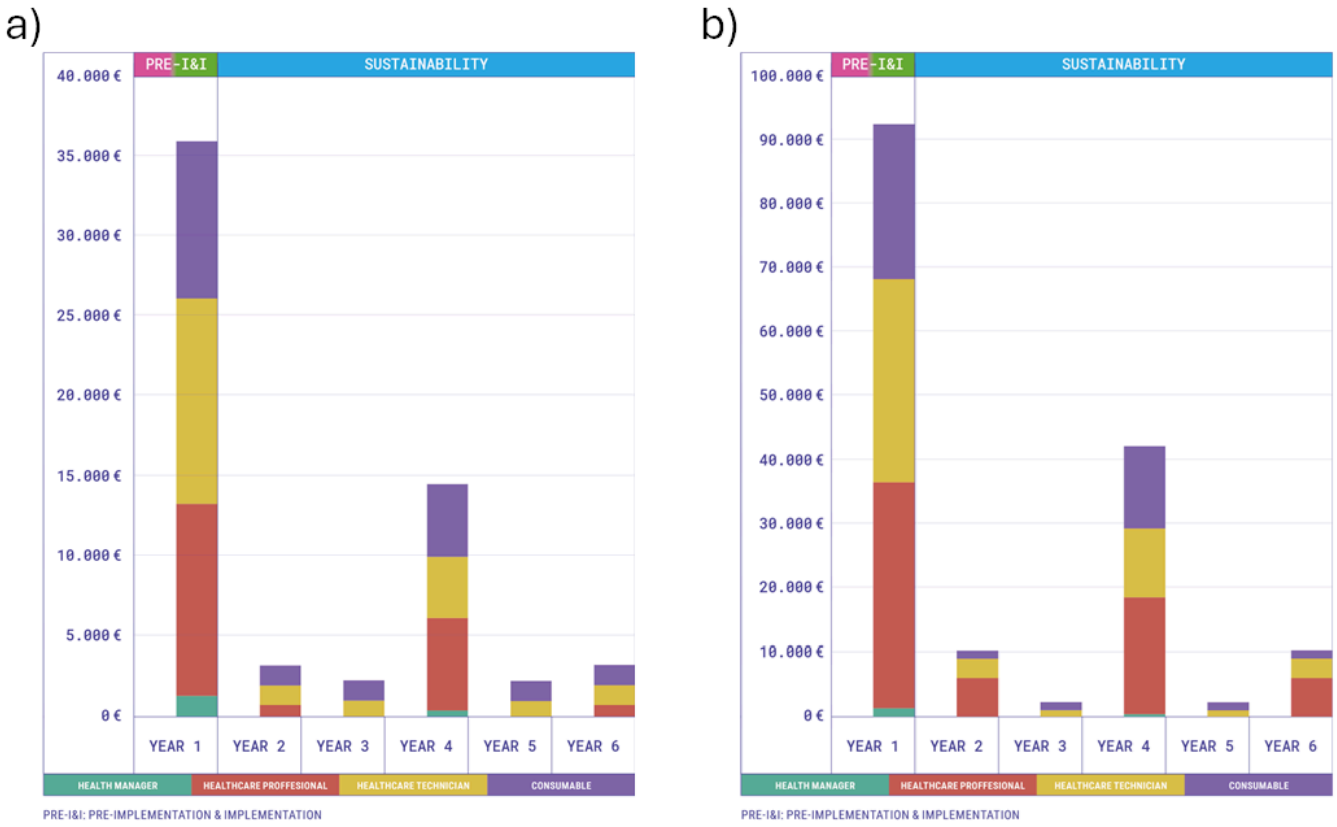


Figure 3

Annual cost by professional role in 12 (a) and 100 (b) PC centres.