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Implementing digitally enabled integrated healthcare

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Abstract

Purpose – The European funded project ADLIFE focuses on the application of digitally enabled integrated care for people with advanced chronic diseases. The implementation of the ADLIFE intervention required a robust practical tool that would be common to all pilot sites while allowing flexibility for local variations as well as the ability to adapt to unanticipated changes and problems.

Design/methodology/approach – The ADLIFE project combined the concepts of implementation research and formative evaluation with the standardized operating procedures (SOP) methodology. The ADLIFE project significantly modified the SOP approach and used it as a means to not only to define and organize the tasks that needed to be performed in preparing and implementing the ADLIFE intervention but also to create a deeper understanding of the unique challenges faced in each site, as well as a method for achieving a consensus.

Findings – The ADLIFE SOPs were developed by a dedicated working group, and they encompassed the preparatory phase leading up to implementation of the intervention. The SOP was also the basis for monitoring the implementation, and this created a structure for the dynamic ongoing tactical and even strategic changes necessitated by local diversity as well as many unanticipated changes.

Originality/value – The SOP methodology was useful in supporting the development of the ADLIFE SOP, which was a consensus-based approach to guide for managing the implementation process, both at project and local levels. It has supported continuous improvement and learning throughout the project.

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Both the process and the SOP produced by the process can be readily adapted and used in other similar projects.

Keywords Integrated provision of care, Care and support, Chronic care, Integrated care, Continuity of care
Paper type Conceptual paper

Background

ADLIFE is a European funded project, running from January 2020 to November 2024, and focusing on the application of digitally enabled integrated care for people with advanced chronic diseases, specifically advanced congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). Its aim is to implement an integrated care process, supported by digital tools, for joint patient care planning, enabling collaboration of care among all healthcare stakeholders and supporting patient/carer empowerment and shared decision-making. The main digital tools to facilitate the integrated care process are a digital patient care planning platform, a clinical decision support system and a digital patient empowerment platform, which together comprise the ADLIFE toolbox. Large-scale pilots of the ADLIFE approach are being implemented in five countries.

As in all digital health innovations there is, and should be, an intimate connection between the new digital tools and the changes they trigger to the actual delivery of health care services. Thus, to be successful and to deliver real health systems and patient value, such services require not only deployment of technology but also service redesign, wherein the focus on the role of the digital tool is but one feature of a reinvented configuration of health services (Shaw *et al.*, 2018).

As with the implementation of all innovations in healthcare, intended to effect positive change in care pathways and health outcomes, integrated care is notable for its complexity as it is meant not only to enhance the method by which patients and clinicians communicate, but also the active involvement of a variety of healthcare providers in collaborating in ways that enable joint decision-making and more coordinated care delivery. There are also additional key challenges such as achieving interoperability and concepts of security and privacy in context of digital health models of integrated care (Pant *et al.*, 2022).

In ADLIFE, the challenges of innovation implementation are magnified by the need to implement the technology and associated services in 6 very different healthcare systems. This confers the benefit of learning how adoption and appropriate changes might be designed in diverse contexts, taking advantage of the existing opportunities and maximizing the potential of the resources in the broadest sense.

There are a great many published articles about implementation methodologies and frameworks including: PARIHS (Kitson *et al.*, 1998; Harvey and Kitson, 2016); Observed Knowledge Translation Application Process (OKTAP) (Berta *et al.*, 2010); Knowledge to Action model (Graham *et al.*, 2007) and Consolidated Framework for Implementation Research (Damschroder *et al.*, 2009), to mention a few. Increasingly, there is an emphasis on using "implementation science" to support the deployment of digital health innovations and particularly "formative" research, with its emphasis on making necessary changes (and documenting them) during the course of implementation, such as PDSA (Plan Do Study Act) (Moen and Norman, 2009) and other quality improvement strategies (The Health Foundation, 2021) as well as maturity models (Sinn *et al.*, 2022). As Nick Goodwin, past director of the International Foundation for Integrated Care and currently Director Central Coast Research Institute Office PVC–Health, Medicine and Wellbeing in Australia, put it, the engine room of successful integrated care programs, as complex service innovations, requires a cycle of improvement since making progress is always nonlinear and usually a messy affair (Goodwin, 2019). The objective of this paper is to present the evolution of the implementation methodology used by the ADLIFE project and its potential contribution to enhancing existing implementation methodologies and frameworks.

Methodology

The implementation frameworks cited above tend to be broad approaches that do not spell out step-by-step activities required to actualize them in practice, specifically in implementing complex interventions such as digitally enabled integrated care. In order address this gap, the ADLIFE project chose to use the standardized operating procedures (SOP) approach as its implementation framework. An SOP traditionally is a set of written instructions that describes the step-by-step process that must be taken to properly perform a routine activity. SOPs are meant to be followed the exact same way every time to guarantee that the organization remains consistent and in compliance with industry regulations and business standards (Brush, 2021). SOPs are used across all industries. Many organizations use dozens of them to ensure consistently high-quality work across the entire team (Gaskin, 2022).

In considering the use of the SOP approach, we noted that SOPs have been increasingly used in healthcare. It is used in clinical research where the focus is set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects, or in actual patient care such as triage, when limited resources get used according to an assessment on ranking, urgency and staffing possibilities (Raytheon Polar Services Company, 2006). For example, emergency room physicians have SOPs for unconscious patients. Nurses in an operating room have their own SOPs when handing over devices to the surgeon (https://digitalismedical.com/blog/standard-operating-procedures-in-healthcare/).

Other factors that contributed to the choice of the SOP approach are that it was used successfully in ADLIFE's precursor project, C3-Cloud (von Tottleben *et al.*, 2022) to ensure that the pilots adopted a standardized approach to running the pilot during the project. More recently, SOPs have been used in the implementation of virtual care that is a significant element in ADLIFE. Examples from the National Health Service (NHS) in England are the Walsall Covid Safe at Home SOP (Roberts and Ankcorn, 2021) and the Standard Operating Procedure for Leicestershire Partnership NHS Trust and University Hospitals of Leicester NHS Trust Covid-19 Virtual Community Ward Service (Standard Operating Procedure for Leicestershire Partnership NHS Trust and University Hospitals of Leicester NHS Trust Covid-19 Virtual Community Ward Service, 2020).

Moving toward a broader use of SOPs at larger project levels, in 2014, the World Health Organization (WHO) African Regional Office developed an SOP for coordinating public health event preparedness in the WHO African Region (WHO, 2014). Even more similar to the ADLIFE project is the Standard Operating Procedure for Implementing "Patients Know Best [PKB]" in Primary Care in Nottinghamshire, England (Standard Operating Procedure |Primary Care | Implementing Patients Know Best [PKB], 2020).

The challenge of implementing digital technologies to support integrated care processes, in very diverse healthcare systems, is daunting. Care provision in each system is organized differently: the role of primary care is different; the relationship between specialists, hospitals and primary care is different; how healthcare professionals are reimbursed is different. Likewise, there are significant differences in the digital systems that support healthcare. The SOP methodology has the advantage of being systematic, structured, straightforward and practical. When you define an SOP, you define tasks that must be performed to achieve your desired outcomes, including how to proceed when there is a deviation from the defined standard procedure. SOP enables an administrator to organize personnel, information, and tasks in response to events and incidents in order to achieve comprehensive control of the operation. There exists a plethora of templates available, which can be adapted to a project's specific characteristics and needs. An essential corollary of the project-level SOP are the manuals of procedures (MOPs, sometimes called work instructions) that are developed by and for each pilot site to describe the detailed processes and tasks at the local level within the context of the overall project SOP (Fonseca, 2022).

The ADLIFE project significantly modified the SOP approach and used it as a means to not only to define and organize the tasks that needed to be performed in preparing and

implementing the ADLIFE intervention but also to create a deeper understanding of the unique challenges faced in each site, as well as a method for achieving a basic level of consensus. The essential activities defined in the SOP served as a basis for the monitoring and tracking tool. As the realization dawned that there would be many unanticipated challenges requiring "changes as you go," both at project and individual site level, the monitoring tool concept was expanded to track "actual vs planned" for the real-life implementation of the pilots. In effect, ADLIFE married the concepts of implementation research and formative evaluation with the SOP methodology.

Results

The ADLIFE pilots

The original plan was to implement the ADLIFE intervention in seven regions (five in regional public health systems Basque Public Health Service in Basque Country in Spain (OSAKIDETZA), Region Jämtland Härjedalen in Sweden (RJH) (that eventually withdrew from the project), Odense University Hospital in Denmark (OUH), University Hospitals Coventry and Warwickshire NHS Trust in England (UHCW), NHS Lanarkshire in Scotland (NHSL)) and two healthcare providers in social health insurance systems: (a) Gesunder Werra-Meißner Kreis (GWMK) in Hamburg, Germany and (b) Samson Assuta Ashdod Hospital with Maccabi Healthcare Services–Southern Region (AMCA) in the Ashdod District in Israel. In the Basque Country and Sweden, all the healthcare professionals are salaried employees of the public health system. In Denmark, the UK, Germany and Israel, healthcare professionals in hospitals are generally salaried employees, but GPs (as well as specialists in Germany and Israel) are independent practitioners, by and large working out of their own private clinics with some level of contractual relationship with the State, the Region or the Healthcare Insurer, which differs from country to country. This has created some unique challenges. The level of digitization of the healthcare system, i.e. electronic medical records and sharing of essential patient data across organizational boundaries, is relatively high, although variable, in all pilot sites with the exception of Germany where the digitization of healthcare lags behind. However, even in the sites with the highest levels of integration, joint patient care planning and ongoing care integration – particularly between the hospital and primary care – as well as the patient and family, remains a challenge. Hence, the focus of the ADLIFE process and toolbox was to meet this challenge.

Building the ADLIFE SOP – the process

The process of developing the ADLIFE SOPs began in the early stages of the project, with the establishment of a dedicated working group (WG) made up primarily of representatives of the pilot sites, but also including key technical partners responsible for developing and/or refining the digital tools to be deployed to support the integrated care processes. After some initial scoping meetings in the first year, the WG met remotely every two weeks from the start of year two, in order to develop the SOP and to begin considering if site specific variations might be necessary. Properly embedding a digital health innovation into a health system, its ICT environment and into care pathways is a complex intervention and this level of engagement was necessary and proved valuable. The process of preparing the pilot implementation began with "Change Management" wherein the WG members jointly defined the focus areas for change management and the approach to facilitating and managing the change. It was clear that we could not achieve total service transformation with this one project, and we therefore chose to focus on three key areas for change: The communication, joint decision making and care planning between the hospital and primary care staff; the role of the Nurse Care Coordinator/Care manager; and shared decision-making of professionals with the patient and his family. This decision not only guided the change management

process but provided the foundation for the development of the project SOP. Many of the SOP activities were predicated on the change management process which was also informed by interviews with key stakeholders during the course of the project, as described in the ADLIFE Deliverable 6.2 (Hestner *et al.*, 2022). Each biweekly meeting was prepared with a clear agenda focusing on issues raised by group members and PowerPoint presentations that were shared in advance. Each meeting concluded with action points and a detailed meeting summary. The importance of raising problems, issues and challenges, discussing them together and achieving consensus on the approaches to addressing them, cannot be understated.

The ADLIFE SOP

The ADLIFE SOP begins with the preparatory phase leading up to implementation of the intervention and ends with the completion of the pilots and the evaluation. As such, the ADLIFE Research Protocol (García-Lorenzo *et al.*, 2023) forms the basis for the SOP that focuses on how the Research protocol will be implemented in very practical terms. The ADLIFE SOP is comprised of the following sections:

(a) Approvals (e.g. ethics committee approval, governance approval, data security approval).

(b) Management (e.g. appoint pilot site manager, team, define roles).

(c) Pre-pilot Checklist (tasks to be performed prior to site implementation with deadlines).

(d) Change Management (tasks for facilitating necessary changes).

(e) Implementation of the pilot (recruitment of professionals, patients, training, etc.).

(f) Study Operation (e.g. initial and follow-up visit protocols, use of digital tools).

(g) Conducting the Pilot Study Evaluation (data collection guides, data processing).

(h) Closure – End of Pilot Study/Closure (informing sites and regulatory bodies, data archival).

The detailed subheadings for each of the above seven sections can be found in Table S1 (supplementary table). The overall outline for the SOP was easily agreed upon; however, the details under each section were arrived at transactionally. As each pilot site began to write their local MOP, they identified activities and steps that needed to be taken, at least in their site, and these were then discussed at the WG meetings and where relevant at project level, integrated into the over-arching project SOP.

The monitoring and tracking tools

The monitoring dimensions were based on the SOP. For each dimension we defined the following items for each site: deadline, responsible person, SOP group, SOP subgroup, SOP section, description, status, follow-up/comments/solutions. An Excel file was created on the project's secure collaboration platform (Microsoft SharePoint) so that each pilot site could document its progress on an ongoing basis (see Figure 1 for an example of the Tracking Tool). The monitoring process, supported by the tracking tool and, even more, by the discussions in the biweekly meetings, had several key objectives:

(1) To make sure that all the sites were moving forward in their preparations for the pilot in accordance with the SOP/MOP.

(2) To identify problems, obstacles, issues, particularly unanticipated ones as a basis for joint problem-solving.

(3) To enable agreed upon changes to the originally planned decisions and processes in light of real-life issues encountered in the pilot sites as well as in the overall project.

Deadline	Responsible	SOP Group	SOP sub-group	SOP section	Description	OSAKIDETZA	Follow up / comments / solution
30/11/2022	Pilotsites	Preparation	Approvals and Agreements	Local ICT and Data Security Approval		closed	We have a signed contract with the ICT provider for the structure we need for th development of the predictive model for the intervention. This implies that there an approval 21000208_ADLIFE.pdf
30/11/2022	Pilot sites	Preparation	Approvals and Agreements	Data Protection Impact Assessment (DPIA)	Approvedby Osakidetza´sDPO	closed	DONE: Approvedby Osakidetza´sDPO: EIPD proyecto ADLIFE.compressed.pdf
30/11/2022	Pilot sites	Preparation	Approvals and Agreements	Agreements with Local ICT department	Clear agreements with Local ICT departme on interfaces with the ADLIFE platform, hosting data, keeping data foADlife patients identifiable and trackable	closed	We have a signed contract with the ICT provider for the structure we need for th development of the predictive model for the intervention. This implies that there an approval 21000208_ADLIFE.pdf
30/01/2022	Pilot sites	Preparation	Approvals and Agreements	Governance approval	Not applicable	closed	NOT APPLICABLE
31/01/2023	Pilot sites	Preparation	Approvals and Agreements	Data Processing Agreement (DPA)		in progress	IN PROGRESS. To be closed before the intervention. Osakidetza is checking the standardclassusesin order to add the information it considers necessary to the annexes.

Source(s): Authors' own work

Figure 1.
Monitoring and tracking tool (example)

(4) To document the implementation of the preparations for and the operation of the pilots – actual vs planned, as a basis for lessons learned to support sustainability, scaling up and transferability of the ADLIFE intervention.

In short, the monitoring process, based on the SOP defined tasks, created a structure for the dynamic ongoing tactical and even strategic changes necessitated by a great many unanticipated changes.

Discussion

The ADLIFE Project and particularly the preparation for and implementation of the ADLIFE intervention faced a few challenges unique to digitally enabled Integrated Care and greatly exacerbated by the COVID-19 pandemic, which began 3 months after the start of the project in January 2020. The following are some selected examples.

(1) Crisis in primary care – The first objective in our change management plan was to facilitate and improve communication, joint decision making and care planning between the hospital and primary care staff. The original intent in the pilot sites was to have primary care be the pivot of the pilots. One of the effects of the COVID-19 pandemic was the creation of a crisis situation in primary care, as in many places, desperate to keep people out of the hospital, tremendous burdens were placed on primary care. The situation was most acute in NHSL, who shifted the locus of the project to secondary care, but this was also reflected in the other pilot sites which modified planned processes to ease the burden on primary care.

(2) Changing role of the nurse – This is to some extent related to the primary care crisis, although the contributions of nursing skills within healthcare delivery have been slowly evolving over decades. While Israel foresaw a central role for the Nurse Care Coordinator early on, as we progressed towards the pilot implementation, most of the sites also came to recognize that the integration of the care and the coordination of the multidisciplinary team would rest largely on the shoulders of the Research Nurse Coordinator or a similar role. While there is some variation among pilot sites, the role, in the final instance, of the nurse care coordinator (as opposed to, for example, the primary care doctor) was close communication and follow -up of changes in patient status and patients' adherence to the care plan, as well as the facilitator of communication and coordination among care team members. This required a shift in how the ADLIFE digital planning care platform would be used, by which healthcare professionals and for what functions.

(3) The use of the ADLIFE digital toolbox in the pilots also underwent some reality orientation. The intent was to use it with all its functionalities, based on the detailed storyboards of the sites, side by side with existing digital systems in the pilot sites. In-depth meetings with Healthcare Professionals (HCPs) recruited to the pilots led to decisions that some of the functions of the ADLIFE platform would not be used, but instead existing local tools would be used. An example of this was messaging among the healthcare professionals. Most of the sites already had some form of messaging function built into their local systems. Some of them also had very well-established tools for communicating with patients. It was therefore agreed that the focus for use of the ADLIFE digital platforms in most of the sites would be creating and updating the joint patient care plan–supported by the Clinical Decision Support system, communicating the derived tasks to the patient empowerment platforms with reminders and responses to the patients, reporting health status (including biometric

measurements and selected questionnaires responses) by patients and monitoring patient reported data.

Although the setup of health systems and the relationship between provider organizations, the specifics of care pathways and the roles of different professionals within them vary between countries and locations, the overall process of digital transformation includes many common challenges that are not so different among sites. The working group members found that the regular dialogue to discuss the fine detail of how the ADLIFE solution should become well integrated at their sites enabled these commonalities to surface, and for shared ideation and insights within the group and for emergent practices to be shared. An important part of this process has been for the technology development partners to listen to and understand the adoption pre-requisites, challenges and needs, which proved supplementary to the formalized requirements that were documented early in the project. They were able to adapt their implementation to optimize them for site acceptance and smooth adoption.

The result has not only been to now have an SOP document, enabling deployments and evaluations to be as consistent as is appropriate, but to have been through a collective process of working out good practices in operationalizing digital transformation for patients needing advanced heart failure and lung disease care, including how to strengthen the culture of patient empowerment. We anticipate that the ADLIFE solution is itself better for having been tested in theory through this kind of "think aloud" process, before its actual use.

Conclusions

The SOP methodology was found to be a very useful approach for supporting the management of the implementation of the ADLIFE pilot preparation and operation. It is a very good tool for defining both what must be done and how it will be done in very practical terms. However, the strength of the ADLIFE SOP lay in the process of how it was created and subsequently, how it was used. The ADLIFE SOP Manual was a joint creation in which virtually all the partners (both clinical and technical) participated. It was based on the Research Protocol that was jointly created and underwent over 30 iterations. The SOP was constructed virtually by online meetings and emails, with supporting documents and PowerPoint presentations guiding the discussion. As this was done within the context of the WG for preparation of the pilots, these discussions are all documented in recordings and minutes of the meetings, with their accompanying materials. The SOP manual represented the consensus of the entire consortium of 12 partners from different countries, healthcare systems, research regulations and technology levels. It was understood from the beginning that there would be local variations and that it would be modified as we learned new things and met unanticipated challenges. The ADLIFE consortium was committed from the outset to a "formative" process. In short, the ADLIFE SOP was not a set of dictated rules, but a compass, a guide designed to keep us going North despite tempests and squalls – and there were many.

Implementing integrated care processes along with supportive digital technology is still a significant challenge and even more formidable when the implementation is multicenter across different countries. The use of a consensus-based SOP approach as the guidebook for managing the implementation process is very useful, both at a cross-country project level and at the local level. Using the SOP dimensions for monitoring and tracking implementation can support the formative evaluation process – by gathering and analyzing feedback during the development and implementation stages, identifying strengths, weaknesses and areas for improvement, with the aim of making adjustments to improve the quality and effectiveness of the intervention. In the ADLIFE project, it has, in fact, supported continuous improvement and learning throughout the project.

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a. Approvals
   - Local ethical committee approval
   - Local ICT and data security approval
   - Clear agreements with local ICT department on interfaces with the ADLIFE platform, hosting data, keeping data for ADLIFE patients identifiable and trackable
   - Governance approval
   - Data Protection Impact assessment (DPIA)
   - Data Processing Agreement (DPA)
b. Management
   - Appoint a pilot site manager
   - Appoint a pilot site team
   - Define pilot site team members roles and responsibilities (the same person may have multiple roles)
     - o Clinical lead
     - o Nurse lead
     - o ICT lead
     - o Training lead
     - o Research lead
     - o Communication lead
c. List of tasks to be performed prior to site implementation with milestones/deadlines
   - ICT related activities – list and define
     - o Infrastructure design and implementation
     - o System installation, support and maintenance
     - o System testing
     - o Data management, integration and data extracts
     - o Business continuity and disaster recovery
     - o System security and user access
   - Translation of stakeholder pre-pilot interview guidelines
   - Preparations for the recruitment of professionals
   - Translation of platforms, guidelines, questionnaires etc.
   - Preparation of data base of potential patients for intervention and control group
   - Preparation of material for recruitment of professionals
   - Preparation of information materials for recruitment of patients
   - Preparation of training materials (manuals, slides, videos) for professionals and patients
   - Set up a "help desk" for supporting both professionals and patients/carers both for ICT-related and process-related issues. Appoint the people, define what they will do, how they can be contacted
   - Other tasks
d. Change management
   - prepare internal information and communication materials about the project
   - Meet with upper-level management people to provide updates on the project. Identify support need from them and ask for it
   - Meet with key stakeholders
e. Implementation of the pilot
   - Recruitment of professionals
   - Training of professionals
   - Providing professionals with their list of patients that meet inclusion criteria
   - Selection of patients to be approached
   - Define patient recruitment process for your site
   - Training of patients and carers

(*continued*)

Table S1. ADLIFE SOP outline (headings and subheadings)

f. Study operation
- Document electronic systems – informing MDT staff about how the ICT systems will work and how they will use them
- Initial visit protocol – specify the process for scheduling clinical appointments for study patients
- Follow-up protocol – specify the process for scheduling follow-up visits, and *the process for unscheduled care*, especially how to inform other clinicians that the patient is in our study, if they attend spontaneously, and what other clinicians might be expected to document differently to support the study
- Patient self-management and empowerment – how will this work, what devices if any will be used, how patients will be able to upload readings directly from personal sensor devices, e.g. blood pressure readings or if they are using regular devices, how will they enter the measures manually, complete questionnaires, report symptoms

- Handling of patient queries
  - o Clear contact points and guidance for enquiries about;
    - The research project
    - Use of the PEP
    - Self-management and wellness queries
    - Potentially serious health concerns
  - o Documenting interactions with patients
- Dealing with issues
  - o If the system is not available, based on SLA, the webpage should provide a suitable message and contact details
  - o Agree on how participants get notified
  - o Agree on how issue gets resolved
- Multi-disciplinary team interactions (define how this will work in your site. Will their interactions be by telephone, videoconference, email, instant messaging, messaging using the PCPMP?). In all instances, how will interactions or the results of the interactions be documented?
- Withdrawal from the study
  - o Withdrawal from the study–health Centers/Organizations
  - o Withdrawal from the study – MDT members
  - o Withdrawal from the study – Patients

g. Conducting the pilot study evaluation

Table S1. **Source(s):** Authors' own work

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