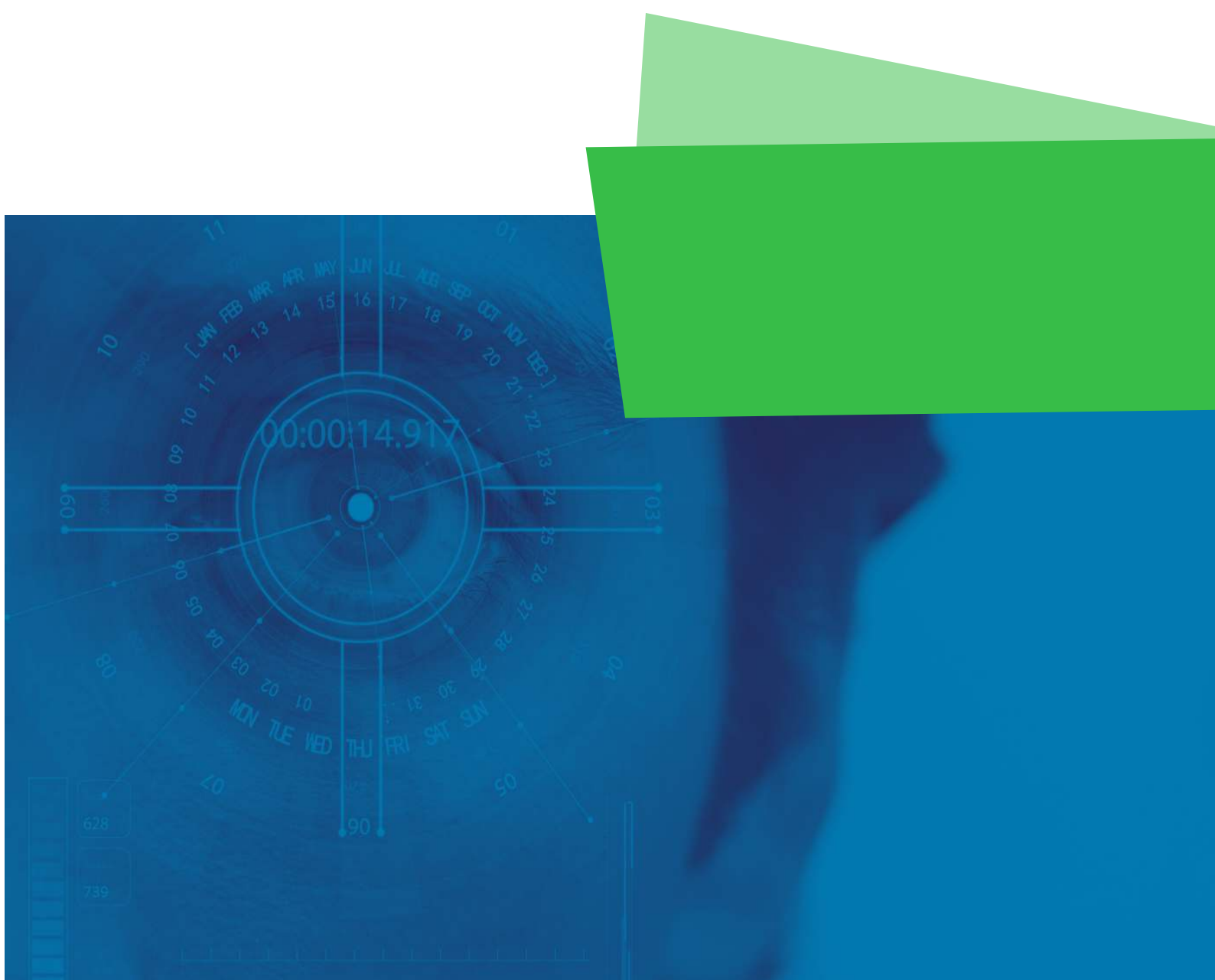**CAIDX TOOL #6**

IMPLEMENTATION AND CHANGE MANAGEMENT GUIDE

For implementation managers responsible for integrating AI solutions in clinical settings.

Content

Background

Change management (CM) is a systematic approach to managing the transition or transformation of an organisation's goals, processes and technologies. Change management is critical to the implementation of artificial intelligence (AI) in healthcare because it addresses the human, organisational and technical challenges that often accompany technological change. The successful and sustainable implementation of new technologies often depends on non-technical and, in particular, invisible aspects, as illustrated by the "iceberg metaphor" in Figure 1. Here, the classic project management triangle of cost - quality - time is "above sea level" and below it are the hidden aspects such as attitude, acceptance and behaviour. These are often not openly communicated and therefore difficult to manage.
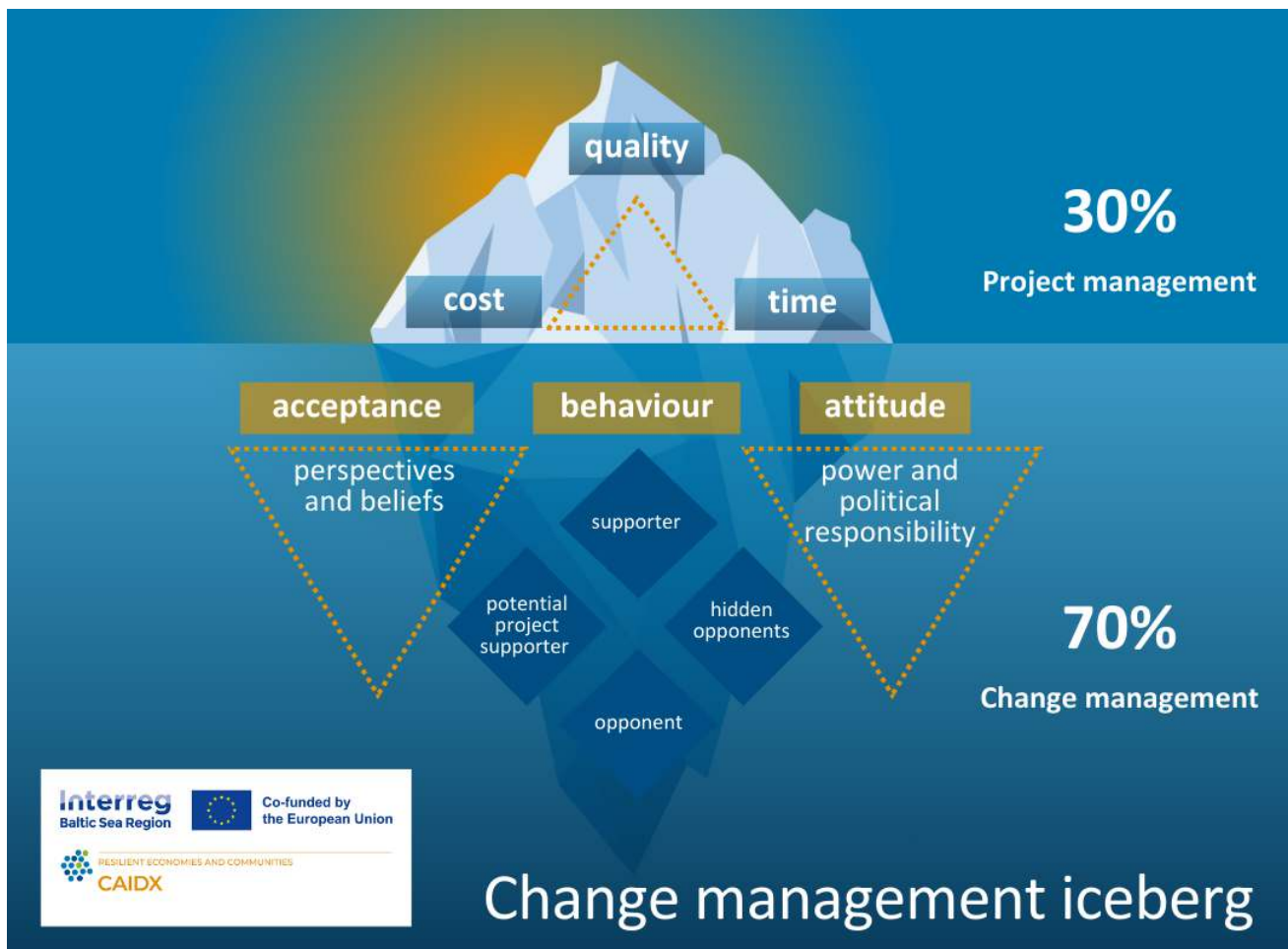
The CAIDX Implementation and Change Management Guide (ICM) guide aims at providing a framework to manage these hidden aspects of implementation by addressing the human side of the implementation with a focus on the specifics of artificial intelligence.

Here are some key reasons for the importance of change management in the context of AI implementation:

1. **Building Trust and Reducing Resistance**: Healthcare professionals may be hesitant to adopt AI due to fears of job displacement, workflow disruption, or concerns about AI reliability. Effective change management involves open communication, involving end-users in the process from the start, and addressing their concerns, which builds trust and reduces resistance to AI adoption.

2. **Integrating AI into Existing Workflows**: AI implementation often disrupts established clinical workflows. Without proper change management, these disruptions can lead to inefficiencies and frustration. A strategic change management plan ensures AI tools are integrated smoothly into daily practices, minimizing disruptions while enhancing efficiency.

3. **Facilitating Multidisciplinary Collaboration**: Successful AI implementation requires coordination across multiple teams—e.g. clinicians, data scientists, and IT professionals. Change management creates structured processes for collaboration and communication, aligning all stakeholders around shared goals.

4. **Sustaining Long-Term Success**: AI systems require continuous learning, adaptation, evaluation and maintenance. Change management promotes ongoing education and support for healthcare professionals, ensuring that AI tools are not only adopted but used effectively and sustained over time.

The methodology used here is the well-known Kotter's 8 steps for leading change that is the most frequent used methodology in healthcare due to a recent review.

General principles

For a successful implementation it is recommended to respect the following principles:

1. There should be a responsible person who oversees the implementation and change management process.

2. It is highly recommended to involve the end-users from the beginning of the development process. Input from the end-users can provide insight into their specific needs in their daily routine and how the AI technology should be accessible in the specific tools they use.

3. It is important that end-users understand how the AI technology works on a conceptual level, and how it will change their work process.

4. Communication is key! Start communicating the intended change very early in the process.

5. Create an inventory of the different involved groups and discuss their different perspectives towards the change process.

6. Ensure that there is a sense of mutual respect and that everyone is heard throughout the process.

7. Ensure enough resources and time to have a secure and successful implementation process.

8. Ensure that on-the-job-training is provided to educate and train the involved personnel.

9. Ensure that it is clear what the new AI technology is and how it works.

10. The developer of the technology should therefore be able to highlight how the AI-technology works in the system, and how it will influence daily practice for the healthcare professionals.

11. Make sure there is a process where to go if there are any concerns with the output/results from the AI-technology.

Target group of the ICM Guide

The guide is primarily written for implementation managers responsible for integrating AI solutions in clinical settings i.e. the change manager. However, it is also valuable for companies to get an understanding of the steps necessary for successful implementation.

Furthermore, it is important to remember that this document is a guide towards implementation through change management. This relies on commitment towards change from those involved. Since this is not always the case there will be a focus on risks and solutions for each stage. Additionally, not all aspects may fit into your organization, however, the sentiments should be fairly aligned with most organizational structures. Every process is not going to be similar and cannot be transferred as one to one.

How to use the ICM Guide

The CAIDX ICM Guide is organized around **3 phases: plan, implement, assess.** The 8 steps of the Kotter model are mapped to these 3 phases. Not all of the issues and recommendations mentioned here will be relevant in every case. They are generally important concepts that should be considered. Whether they are relevant to a specific application must be decided by the person responsible for implementation.

The guide is written for a situation where an already certified product is procured and about to be implemented in a clinical setting and in most cases into an existing workflow. I this situation you are in phase 5 of the CAIDX clinical AI pathway model. Make sure to consider all relevant technical aspects described in the CAIDX clinical AI pathway model. The CAIDX ICM Guide only takes the human aspects into account.

Kotter's 8 step model applied to AI implementation

The CAIDX ICM Guide uses the Kotter 8-step model as a methodology to guide the user through the change management aspects of implementation. If you are familiar with a different methodology, feel free to use your methodology and consider our AI specific recommendations.

The Kotter 8-step model is embedded in the 3 phases: plan, implement, assess. These are added as an extra layer of organisation. The planning phase includes the first four steps, the implementation phase consists of steps 5, 6 and 7, and the assessment phase includes step 8. This phase continues throughout the lifecycle of the AI system.

Due to the risk of model or data drift, the performance of the AI system should be constantly monitored. It is also important to monitor the use of the system and any signs of deskilling or automation bias among team members.
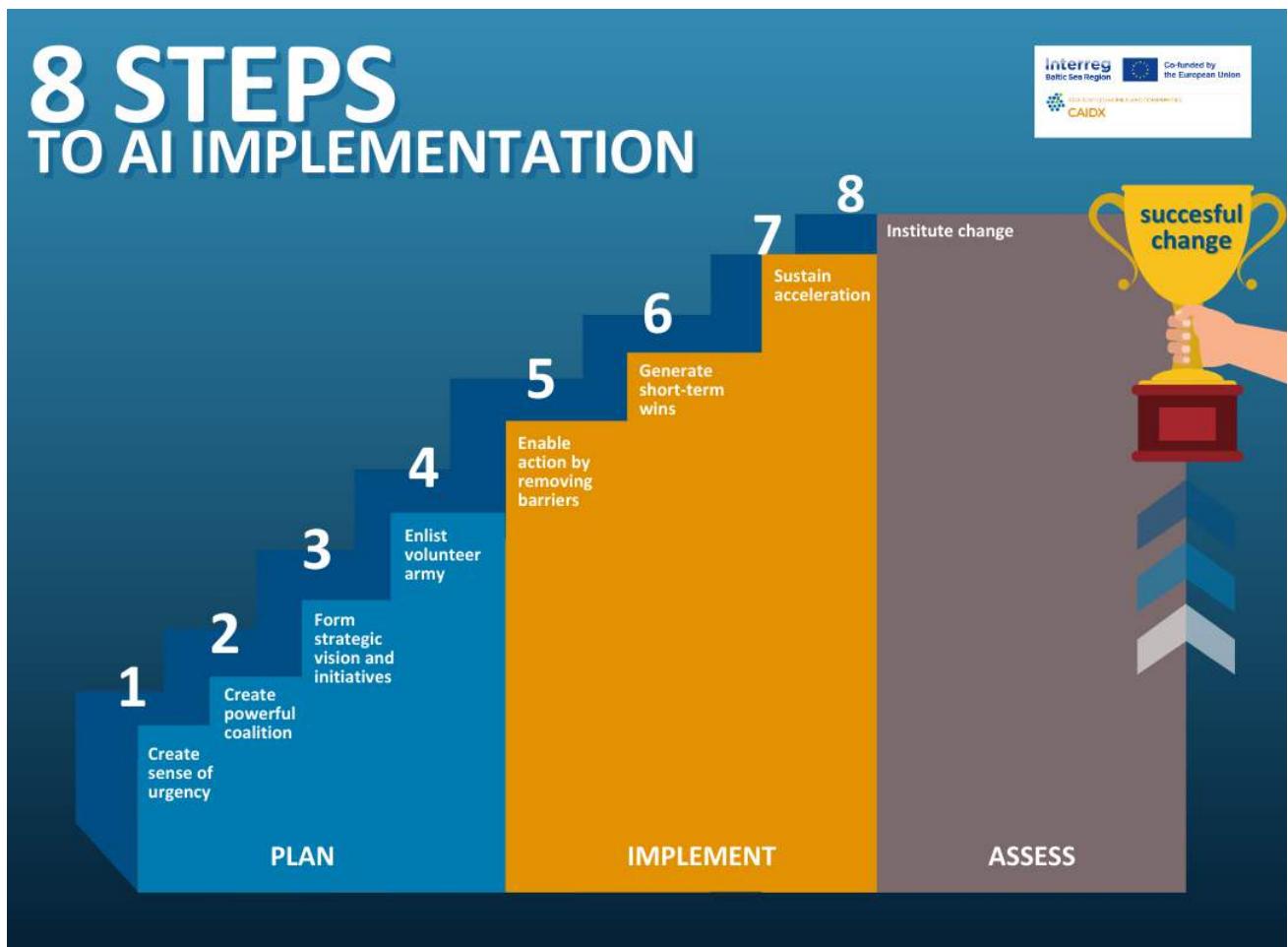
Phase 1: Plan

Purpose: The planning phase covers the first 4 steps of the Kotter model. For successful implementation it is essential to have a common understanding of the technology, the new workflow, the benefits, and the potential risks. All relevant people should be involved in the planning process, and it is important not to leave anyone behind.

Outcome: At the end of this phase, there should be a common understanding of what the specific AI technology can do and why it is necessary for the hospital. Important elements at this stage are to have an established steering group with different representatives to ensure that there is direct contact with all stakeholders and that all necessary departments are involved in planning the process. They should agree on a vision, strategy and communication plan. The hospital should identify who in the department could be an end-user representative and who will be the first users to work with the technology. It is recommended to plan in cycles, starting small and then expanding.

Potential risks and solutions

Risk: That there are not enough resources to handle this project.

Solution: Focus on freeing up resources before this stage. In addition, the process should start before final decisions are made to test or purchase the technology.

Risk: Someone is included who does not have the desire for AI-technology.

Solution: It is important to have defined why AI-technology is relevant to the department and what the benefits will be before inviting the steering group and communicating with the department.

Risk: It is not clear who should take the final decisions and handle administrative tasks.

Solution: Decide that the coordinator should make the final decision on planning, but that the views of the additional representatives should be taken into account.

Step 1: Create a sense of urgency

The very first step in the Kotter model is to create a sense of urgency. To set change in motion, you need a reason. This 'sense of urgency' creates a shared awareness of the urgency or attractiveness of change. This means that the urgency can be based on a clinical need or problem that needs to be solved or on great opportunities. You can also derive the urgency from the question of which scenarios could occur if no change is implemented. The urgency must be strong and serious enough for the employees so that the 'sense of urgency' is also effective in the subsequent stages. Be aware that the new opportunity might also create fear (e.g. will the AI take over my work? Will I lose my job?). Make sure to create an atmosphere of mutual respect and let everyone speak about their fears or attitudes towards the new technology.

Outcome: There should be a common language surrounding the AI-technology, which is agreed upon and understood by all stakeholders. The language and terminology must be clear for everyone, especially between stakeholders with different backgrounds to avoid misunderstanding.

Step 2: Create a powerful coalition

In this step you should look for like-minded people for the desired change. In other words, people in your organisation who have the same or a similar sense of urgency. To turn this group into a leadership coalition, it is important to gather people around you who have charisma and a good reputation within the organisation. The more people from different departments, backgrounds and perspectives, the greater the reach of your leadership coalition. Implementing a new AI-based solution into an existing clinical workflow involves many different experts (e.g. IT, procurement, legal, clinical) and, of course, the end users of the solution. Ideally, each group will be represented in this coalition.

Outcome: Make sure there is enough support to move to the next step. This cannot be quantified. However, there should be a realistic number of stakeholders that support the change.

Step 3: Form a strategic vision and initiatives

In your steering group, you develop strategies and formulate visions of how you as an organisation will deal with the 'sense of urgency'. Especially in 'away from the current situation' scenarios, it helps to have a positive vision of exactly what the future could look like. While an 'away from' can be a strong initial impetus, a vision and 'towards' scenario is much more inspiring. The overarching goals, visions and strategies at this stage of the Kotter Change Management Model provide direction for the next stages and help to implement the change.

Outcome: At this stage there should be a clear strategy and an initial plan of how to organize the change.

Step 4: Enlist a volunteer army

Change is not a project that affects just a few people. Instead, you need to mobilise many colleagues so that the change never reaches the critical 'tipping point'. Communication in Kotter Change Management is not defined by quantity and a few slides. Instead, people need to feel a sense of urgency. The vision and the strategies based on it must be tangible, understandable and inspiring. Only when you have reached and motivated enough people who take the sense of urgency seriously enough and trust your strategy, are you ready for Stage 5 of the Kotter Change Management Model.

Outcome: By this stage you should have a support team in place, including top management support.

Phase 2: Implement

Purpose: At this stage, there should be a good sense of who the first users are, what their roles will be during implementation, and how to deal with problems during implementation. During implementation, there is a need for supervision and close contact with the people responsible. It is recommended to start small and not to involve too many people in the pilot phase. Remember to include staff in follow-up meetings to hear about the obstacles that have been overcome and, where appropriate, to set a date when the AI technology will fully replace the previous solution.

Outcome: AI technology is in use, and all stakeholders have a sense of how this process will continue.

Potential risks and solutions

Risk: Displeasure about the change from those not involved in the steering group.

Solution: Involve the first-users since they are hopefully engaged with the change and can highlight the good things with the implementation.

Risk: Concerns and evidence that the technology disrupts the current workflow.

Solution: Work with the first-users to handle the changes by communicating differently, changing the focus of the training and perhaps extending the implementation plan or timeline.

Risk: The timeline is not being adhered to, leading to frustration.

Solution: To avoid this, communicate why the timeline has changed and how quickly you will be back on track.

Step 5: Enable action by removing barriers

Resistance and obstacles are part of any change and can come in many visible and invisible forms. Unwanted routines, inefficient processes, sub-optimal structures or inadequate technical requirements are obvious barriers that should be removed if they exist. Less obvious, and often not immediately visible, is resistance from employees. However, this can provide valuable information. After all, these employees may be trying to protect something that is worth protecting and that has escaped your attention. In this phase, it is crucial to take resistance seriously and listen to it. Only when you are sure that all resistance has been identified can you decisively remove the obstacles that stand in the way of the vision.

Outcome: At this stage you should be sure that the team supports the new solution and is ready for the change. Everything should now be in place to start planning a pilot implementation.

Step 6: Generate short-term wins

Change is tough and sometimes painful. To ensure that motivation is not lost along the way, the Kotter change management model suggests aiming for short-term wins, making them visible and celebrating them. This means putting the 'big chunks' on the back burner for the time being, focusing on the first tangible milestones, or defining lighthouse projects that promise short-term success. These 'quick wins' build people's confidence in the change and celebrate the first brave people who have successfully embarked on the journey. A small-scale pilot may be the right setting for the first real-world implementation.

Outcome: Successful completion of the first pilot project. Time to celebrate the first success and opportunity to convince those who are still critical or reluctant. Pay attention to their criticisms if they still exist. Perhaps you have overlooked something that needs to be addressed?

Prepare for a larger scale trial or complete roll out depending on the case and the implementation plan.

Step 7: Sustain acceleration

The next step is one of the most critical in Kotter's change management. Don't get dazzled by the successes of phase six too soon. This means that if the first implementation works, it does not mean that the change has been successfully established. Rather than celebrating too soon, it is better to remain vigilant. In other words, you can drive the change forward with the same focus and seriousness as in the first six phases. Take a close look at what has gone well so far and continue to adapt your approach. Make sure no one is left behind. Has everyone been properly trained? Make sure there is an atmosphere of trust within the team and that there is room for skills development.

Outcome: The new solution is in routine use.

Phase 3: Assess

Purpose: There should be continuous evaluation during the implementation process and after each stage. This will also help to assess when it is possible to scale up. The coordinator should be prepared for close monitoring to ensure satisfaction within the department. Recognise the work and communicate the 'small wins' within the department. Be aware that it can take up to 6 months to develop a sense of ownership.

Outcome: At this stage, the implementation process should be nearing completion, there should be a sense of ownership among employees, and there should be a high level of usage of the AI solution in place of previous methods. The solution has become the "new normal". But it is not time to sit back. One of the characteristics of AI technology is that there is no final implementation. Because of its learning nature, the technology needs to be constantly monitored! Even in a frozen state, where no learning and adaptation with new data is allowed, there is a risk of data or model drift.

Potential risks and solutions

Risk: System failures are not reported, or the AI solution is not used, leading to lack of commitment and adoption process.

Solution: In this case, the use should be monitored in some way and there should be check-in meetings where it is emphasised that any problems, large or small, should be reported to ensure a comfortable process for all involved.

Risk: Some choose not to use the system.

Solution: It is important to ask them about their reasoning or help them to become more familiar with the system, especially if the system is untested and the previous methods are being phased out.

Risk: After a longer period of use, there is a risk of deskilling of the team-members and/or automation bias. Solution: Make sure to implement a regular check-up and risk management system.

Step 8: Institute change

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Finally, the process must be embedded in the corporate culture. The technology has been successfully implemented when end users are at a stage where it has become part of their daily routine, and when the previous work routine has been fully transformed into the new routine supported by AI technology. This can take time, and it is important that the company or developer is available to provide support during the initial post-implementation period. This is called the hyper-care phase. The second crucial factor in the eighth stage of the Kotter model is to ensure that there is no relapse into old patterns. Kotter's change management is only successfully completed when the implemented solution has become the new routine workflow.

After successful implementation: continuous monitoring and improvement

Both the company and the hospital should allow time for ongoing monitoring, as well as time to iterate on the technology if there are problems with its use after implementation. This will depend on whether the AI technology is fully developed prior to purchase, or whether the hospital is helping to test and develop the AI technology in collaboration with the company. If it is fully developed, assessments will need to be made about technical support and whether the AI technology fits into clinicians' daily work. It is also necessary to monitor any potential model drift or performance degradation of the algorithm. It is also important to ensure that a roll-back solution is in place in the event of technical problems.

Annex

Practical tips for implementation

The following tips are intended to give an indication of how the implementation process can be carried out. It is recommended to start the first phase as soon as the AI technology has been developed, purchased or before. Throughout this process it is important to consider who should be involved from start to finish. The following order of priority is suggested:

1. Those who are in contact with the technology to be developed and who are affected by it in their daily work. These people should be involved from the very beginning. It is important to select representatives from this group and to communicate with them on an ongoing basis.

2. Those who are in touch with the technology being developed, but who are not affected by it in their day-to-day work. They may have to deal with IT issues related to the AI or help with some tasks. However, they do not need to change their workflow and should be informed throughout the process.

3. Those who have no contact with the technology to be developed and who are not affected in their daily work. They could benefit from a general announcement to inform them of changes in the hospital.

Tasks for the first phase: Plan

☐ Define and invite steering group members (this should be including company/developer, healthcare professionals, IT-department and management).

☐ At the first steering group meeting they should collectively:
- Define who will be affected by the technology and who should be involved.
- Define end-users, ie. Clinicians, should be involved as the first-users?
- Create common terminology for the technology as well as common language surrounding the implementation.

Communication of implementation

☐ Plan meetings with steering group to determine when to start the implementation, as well as the best process for the specific department.

☐ Plan for constant transparency about why this change is happening, how it will happen, how the process is progressing, etc.

☐ Plan communication with the department, as well as larger scale communications.

☐ Prepare to have a common language that is widespread.

☐ Appoint someone who should help with technical support and prepare how to get in contact.

Tasks for the second phase: Implementation

Planning the implementation

☐ Reserve time for meetings with all stakeholders involved, correct involvement and training/understanding the technology.

☐ Invite the steering group to meetings and arrange regular meetings.

☐ Invite the chosen end-users who will be the first-users to understand the AI and teach them how to work with it.

☐ Define the following dates for the implementation process:
- The first day of go-live for the first-users.
- The day of go-live for the remaining department.

☐ Plan training in increments starting with the chosen first-users, who then will help with training of others

☐ Invite all stakeholders to a training session before the rest of the department goes live. The first users should also be invited to help their colleagues with the technology.

☐ Plan to have first-users ready to help when implementation happens and plan meetings with the goal of checking the status.

☐ Define a small part of the department as the pilot group, preferably one with a first-user, then based on feedback scale up.

☐ If needed, adjust the process based on feedback on planning process.

☐ Communicate with all users outside the steering group regarding the technology, training, and implementation plan.

☐ Also celebrate and communicate small steps

Tasks for the third phase: Assessment

Assessing the implementation

- ☐ Prepare to make modifications to the technology and/or the workflow.

- ☐ Do quality surveys on technology and implementation process.

- ☐ Continuous monitoring of the technology use during the implementation:

- ☐ Monitor who is using and who is not using the technology.

- ☐ Deliver feedback between users and developers.

- ☐ Based on feedback define the date when the AI-technology substitutes previous methods (only relevant if not in testing phase)

- ☐ Implement a long-term monitoring regarding skills in the team:
  - Is there a risk of deskilling of your team members?
  - Is there a risk of automation bias?
  - If yes, develop a plan how to react on this

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About the project

The project CAIDX establishes cooperation between artificial intelligence (AI) providers and healthcare institutions to help healthcare professionals integrate AI, and thus improve diagnostics and treatment.

Implementation: January 2023 - December 2025

Project partners

- Innovationsklinikken (Aalborg Universitetshospital) (Lead partner)
- Wroclaw Technology Park
- BioCon Valley
- Tartu Biotechnology Park
- Lower Silesian Centre of Oncology, Pulmonology and Hematology
- Region Skåne
- Innovation Skåne
- Rostock University Medical Centre
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