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Laura Caci, Kathrin Blum, Clara Johnson, Bianca Albers, Lauren Clack, Anna Andritsos, Ana-Maria Anghel, Alberto Antonelli, Athanasios Antoniou, Eirini Apostolidi, Alejandro Ameijeiras, Alessandra Bandera, Lorenzo Biasoli, Teresa Bini, Victoria Bîrluțiu, Greet Boland, Eva Cappelli, Yehuda Carmeli, Elena Carrara, Anna Celotti, Eirini Christaki,

Organizational Readiness for Implementing Infection Control in European Hospitals: Insights from Coincidence Analysis

*Laura Caci[1], Kathrin Blum[1], Clara Johnson[2], Bianca Albers[1], Lauren Clack[1, 3], and the **REVERSE study group

[1] Institute for Implementation Science in Health Care, Medical Faculty, University of Zurich

[2] Department of Psychology, University of Washington, Seattle

[3] Department of Infectious Diseases and Hospital Epidemiology, University Hospital of Zurich

* Correspondence to: laura.caci@uzh.ch

** Members listed after declarations

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Abstract

Background:

Healthcare-associated infections (HAIs) are a threat to public health, however, infection prevention and control (IPC) interventions have been shown to prevent a substantial portion of HAIs. Due to the interrelatedness of IPC intervention components, multifaceted implementation strategies, and contextual factors, IPC implementation is intricate. Organizational readiness for change (ORC) has been labelled as critical to ensure successful implementation, yet it is unclear under which conditions this is the case. We aim to examine if ORC is a necessary and/or sufficient condition for IPC implementation in REVERSE, a study aimed at decreasing multidrug-resistant HAIs in Europe.

Methods:

We conducted a crisp-set Coincidence Analysis on data from the 24 hospitals enrolled in REVERSE to examine necessary and sufficient conditions for IPC implementation. We collected quantitative data on change complexity, implementation leadership, ORC, and sustainability. Implementation strategies used, as well as both theory-based outcomes of initiation and cooperative behavior, were assessed qualitatively. Models were selected based on theoretical grounds, fit indices, and case knowledge.

Results:

Twelve hospitals (50%) had high IPC implementation initiation. We found two alternative pathways explaining this outcome. When hospitals implemented highly complex IPC practices, they needed high ORC levels to initiate change. When complexity was low, ORC did not shape initiation, but sites rather had to show clearly matched implementation barriers and strategies to initiate IPC. Results for cooperative behavior were inconclusive.

Conclusions:

Using a novel cross-case configurational approach, we uncovered the role of ORC for IPC implementation. We found that ORC is of importance under the condition of highly complex

change. When change complexity is low, solidifying ORC is dispensable, and efforts should instead be directed towards a thoughtful and targeted selection of implementation strategies based on identified barriers. These findings have implications for implementers and decision-makers, who may allocate resources based on whether IPC implementation is anticipated to be of high complexity or not, to ensure proper IPC implementation to address HAIs.

Trial registration:

REVERSE was registered with the “International Standard Randomised Controlled Trial Number” (ISRCTN) register under Nr. 12956554 on 11.11.2021, https://www.isrctn.com/ISRCTN12956554

Contributions to the literature

- The importance of readiness for change in implementation has been debated for many years. Our work provides a nuanced understanding of the conditions under which readiness should be considered in implementation efforts in infection prevention.
- We report a thorough, applied example of configurational analysis on qualitative and quantitative data from a multinational trial to address research questions relevant to implementation science.
- Thereby, we showcase the value of using theory, knowledge of the specific implementation settings, and analytical grounds to derive implications and shape future implementation research and practice.

Keywords

Configurational Comparative Methods, Configurational Analysis, Coincidence Analysis, Implementation Science, Infection Control

Introduction

European acute care hospitals face accelerating rates of healthcare-associated infections (HAIs) due to multidrug-resistant organisms, contributing to growing antimicrobial resistance (1). In the 2022-2023 point prevalence survey (PPS, 2), the European Centre for Disease Prevention and Control estimated that 7.1% of all European acute care patients had at least one HAI per day. Annually, 262,833 patients with HAIs were infected with minimum one antimicrobial-resistant bacterium, a 31% increase compared to the 2016-2017 PPS (3). Negative impacts of HAIs include increased length of stay, mortality, health care system costs, patients' financial burden, and long-term disability (4-6). Antimicrobial resistance will keep threatening currently available treatment options for HAIs if this problem remains unaddressed (7).

In Infection Prevention and Control (IPC), several evidence-supported interventions (ESIs) have been identified as effective in preventing HAIs (8). For example, a systematic review and meta-analysis of 144 studies found that 33-55% of HAIs are preventable by implementing multifaceted IPC interventions (9). Even estimations of up to 70% preventability have been described (10). Multifaceted IPC interventions typically include *clinical* and *implementation* components, where clinical components, e.g., hand hygiene indications, are supported by implementation components, e.g., dedicated IPC teams, IPC guidelines, staff training, and other strategies to support individual and organizational changes necessary for introducing and sustaining IPC practices (11, 12).

Although the effectiveness of IPC for HAI prevention has been demonstrated (9, 13, 14), healthcare facilities often struggle to implement and sustain IPC standards (15). The complexity of multifaceted IPC practices may represent a key challenge. Distinct IPC clinical intervention components are often interdependent and influence each other. For instance, active surveillance may trigger isolation measures. Further, their implementation often benefits from multifaceted implementation strategies, i.e., combinations of methods to put IPC interventions into practice (16), rather than single implementation strategies (e.g., education) alone. To ensure quality IPC implementation in healthcare settings, the clinical

IPC intervention components and the multifaceted implementation strategies span across individual, organizational and national levels t, further enhancing complexity.

When implementing complex ESIs, various stakeholders must execute new or altered behaviors (17). Indeed, IPC behaviors are individual (e.g., hand hygiene) as well as collective (e.g., active surveillance), and target different stakeholders (e.g., frontline staff, executive leadership, national representatives). Yet, behavior change theories are underused in IPC implementation studies (18, 19). Furthermore, while IPC behaviors span multiple socio-ecological levels, their implementation primarily occurs within healthcare organizations. Hence, investigating implementation at the organizational level may help to understand what influences behavior change related to IPC implementation (20).

A construct that employs this organizational perspective is *Organizational Readiness for Change* (ORC), defined as, “organizational members’ psychological and behavioral preparedness to implement change” (21, p. 217). According to the *Theory of Organizational Readiness for Change* (TORC, 21, 22), ORC is determined by high change valence (i.e., staff value the change, i.e., its need, urgency, benefit), and positive informational assessment (i.e., staff perceive change implementation as warranted due to task demands, resources and situational factors). Moreover, high ORC results in change-related effort, i.e., timely *initiation* of change behaviors (such as setting goals, planning ahead, identifying steps to start implementing), *cooperative behavior* in change execution (performing activities to reach implementation objectives), and individuals’ *persistence* through obstacles in change implementation . Scholars have used ORC to explain successful or failed implementation of organizational change, and frequently claimed ORC as a critical precursor for implementation (21, 23).

While these claims seem intuitive, the empirical literature supporting that ORC is decisive for successful implementation is scarce. Few ORC measures have been used in empirical studies to investigate the link between ORC and implementation outcomes, leading to a fragmented ORC knowledge base (24-27). However, clarifying the role of ORC in

implementation is relevant for decision-makers and implementation practitioners, as establishing ORC prior to implementation, and maintaining high ORC levels throughout, can be resource-intensive, and may not even be warranted. The current evidence base prevents drawing conclusions if, and under which conditions, ORC is relevant for implementation (24).

One reason for the scarcity of ORC knowledge is that implementation is context-dependent (28, 29), and investigating ORC within diverse, dynamic implementation contexts is intricate. When different variables are at play, e.g., distinct intervention components, implementation strategies, and contextual factors, disentangling the contribution of specific constructs (e.g., ORC) to implementation results is complicated (30).

To find patterns in quantitative or qualitative data, implementation researchers increasingly use Coincidence Analysis (CNA, e.g., 31, 32). As a novel configurational comparative method, CNA uncovers necessary and/or sufficient conditions of an outcome (33-35). Necessary conditions *must* be present, while sufficient conditions *alone* generate the outcome. However, different conditions on alternative *pathways* can lead to the outcome independently (36). Case data from, e.g., individuals, organizations, or systems are systematically compared to identify such conditions. Yakovchenko et al. (37) demonstrate the utility of CNA in their investigation of implementation strategies linked to Hepatitis C virus treatment uptake by identifying five implementation strategy combinations that led to treatment uptake on independent pathways.

Given the interplay of different factors challenging IPC implementation in acute care, CNA may be particularly helpful in identifying patterns contributing to IPC implementation. Contrary to other configurational methods (e.g., Qualitative Comparative Analysis), CNA's algorithmic basis is designed to distill necessary and/or sufficient conditions in data stemming from complex settings, such as acute care (38). The conditions identified in CNA are minimal, i.e., only contain essentials in their outcome explanations (34). This is relevant for implementation in acute care, as recommendations for changing practice preferably focus on essentials. Furthermore, CNA is the only configurational method able to build models with

multiple outcomes, which allows outcome chain analysis, *and*, like other configurational methods, CNA permits qualitative and quantitative data integration (35). Therefore, we used CNA to investigate the role of ORC for IPC implementation in REVERSE (pREVention and management tools for rEducing antibiotic Resistance in high prevalence SEttings)[1], a multinational study designed to address HAIs in Europe.

Our research questions were:

1. What are necessary and/or sufficient conditions for IPC implementation in REVERSE?
2. What is the role of ORC for IPC implementation in REVERSE, i.e., is it a necessary and/or sufficient condition for IPC implementation in REVERSE?

Methods

This article presents the findings of a CNA embedded in REVERSE and is part of a doctoral dissertation on organizational readiness for IPC implementation. The detailed REVERSE implementation methodology is reported elsewhere (39). Where applicable, we utilized the Standards for Reporting Implementation Studies (40). In the absence of CNA reporting guidelines, prior CNA studies guided our reporting (e.g., 34, 37).

REVERSE is registered with the “International Standard Randomised Controlled Trial Number” (ISRCTN) register (Nr. 12956554) and received ethical approval from the Canton of Zurich (AO_2021-00078), and from the 24 hospitals’ ethics committees. Individual survey respondents consented electronically.

Study background and setting

REVERSE is a Horizon2020-funded stepped wedge hybrid type 2 effectiveness-implementation cluster randomized trial aimed at decreasing antimicrobial resistant HAIs in 24 acute care hospitals across Greece, Italy, Romania, and Spain. To reduce HAIs, all hospitals implemented two clinical bundles sequentially: IPC and antibiotic stewardship. For

[1] https://www.reverseproject.eu/

the clinical trial, hospitals were randomized to four staggered cohorts. For this CNA, IPC data were collected before antibiotic stewardship implementation.

The primary implementation aim is to compare an enhanced implementation condition consisting of an *externally facilitated* tailoring strategy, i.e., the prospective selection of implementation strategies based on identified barriers, to *self-guided* tailoring in improving implementation outcomes and HAI rates. To investigate this aim, hospitals were additionally randomized to two implementation conditions: 12 ENHANCED (facilitated tailoring) vs. 12 BASIC implementation hospitals.

Following REVERSE eligibility criteria, the 24 acute care hospitals showed high prevalence of multidrug-resistant organisms based on the 2016/2017 PPS (3). Included hospitals participated with a minimum of 350 inpatient beds, exclusively across intensive care, internal medicine, hematology-oncology, and surgery (including transplant) units. Hospital-based implementation teams collaborated with the REVERSE research teams around data collection and implementation activities.

The term 'REVERSE IPC' refers to the *clinical* IPC intervention components defined within REVERSE (Table 1) and, therefore, do not contain the implementation strategies described in the introduction (e.g., guidelines).

[Table 1]

Conceptual framework

Our work was guided by the TORC (21), with ORC consisting of *change efficacy* and *change commitment*. Change efficacy describes organizational members' perceptions of their collective capability to behave as needed for change implementation. Change commitment captures organizational members' dedication to these behaviors. Two ORC determinants are theorized: 1) change valence, i.e., organizational members' judgements about how valuable, needed, and beneficial the change is, and 2) informational assessment, i.e., organizational members' evaluation of their abilities to perform required tasks, available resources , and

their current situation. Change valence and informational assessment are further shaped by contextual factors including policies, experience, trusting relationships, and organizational culture. The TORC defines that ORC impacts change-related effort as intermediate outcome, which is linked to implementation outcomes, e.g., fidelity (see Figure 1). In this study, REVERSE IPC practices (Table 1) represent the “change” described in the TORC (Figure1).

[Figure 1]

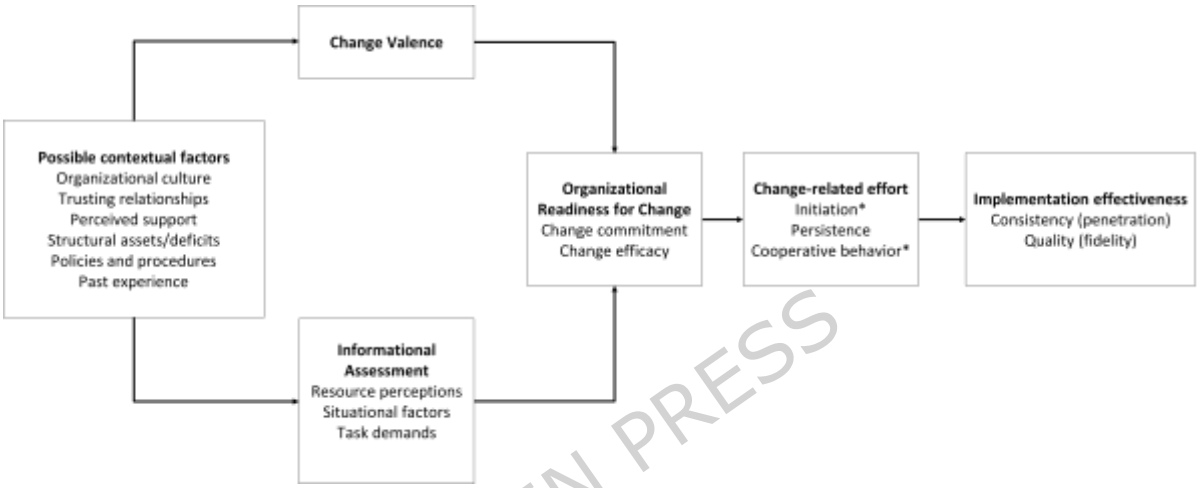

Figure 1. Theory of Organizational Readiness for Change, adapted from Weiner (21). * = CNA outcomes.

CNA outcome and factor selection

First, we selected *outcomes* (akin to dependent variables in traditional methods) and *factors* (akin to independent variables) for inclusion in our modeling. As the TORC theorizes ORC to directly precede change-related effort (including initiation, cooperative behavior, persistence), we selected initiation and cooperative behavior as CNA outcomes, rather than more distal implementation outcomes (e.g., fidelity). We excluded the third direct outcome, persistence, as the scarce guidance to define persistence obstructed its operationalization for REVERSE. We separated factor selection into two phases.

Before data collection, we selected factors based on theory, evidence, and our aim (31, 41), i.e., with ORC as the central factor. Additional factors to investigate in REVERSE were selected through a four-stage approach (detailed elsewhere; 42). We conducted a systematic literature review to map potentially relevant factors for implementation in health care alongside ORC (43). We used the nominal group technique (44) with REVERSE country

representatives to prioritize factors. We then conducted internal implementation team project workshops to determine the final factor set for data collection, all falling under *possible contextual factors* (Figure 1). These were then operationalized by defining their measurement, and the qualitative and quantitative data to be collected for each. The factor selection process is visualized in Figure 2.

[Figure 2]

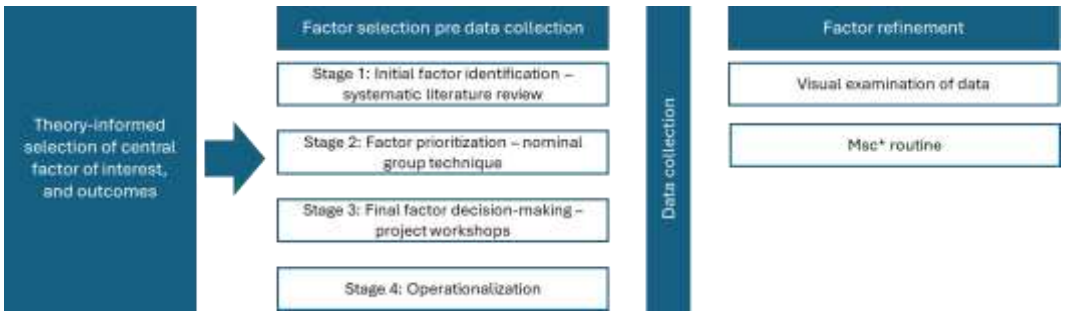

Figure 2. Factor selection procedure. * = minimally sufficient conditions.

The final factor set for data collection included: ORC, implementation leadership, implementation strategies used, sustainability, and change complexity (in the following *complexity*), detailed in Table 2 and Supplement A.

After factor selection, factors were refined as described below.

Data collection

Data were collected between April 2023 and January 2025 with the support of local REVERSE staff. The REVERSE Implementation Tool (RIT) was the basis for qualitative data (45). The RIT is a Microsoft Word document in which REVERSE hospitals regularly tracked their implementation activities, including stakeholder engagement, goals, scope of implementation work, implementation determinants, implementation strategies and monitoring. Hospitals submitted their first RIT six weeks into IPC implementation, and then quarterly for approximately two years. This CNA builds on RITs from implementation year one, with RIT data informing the operationalization of both outcomes (initiation, cooperative behavior) and two factors (complexity, implementation strategies used).

The 12-item Organizational Readiness for Implementing Change (ORIC, 46) scale was used to measure ORC (subscales: change efficacy, change commitment) ranging from 1 ("Disagree") to 5 ("Agree"). The 35-item Clinical Sustainability Assessment Tool (CSAT, 47) (domains: engaged staff & leadership, engaged partners, organizational readiness, workflow integration, implementation & training, monitoring & evaluation, outcomes & effectiveness) was used to assess sustainability on a 7-point scale (1 "To little or no extent" to 7 "To a very great extent"). Implementation leadership was measured with the 12-item Implementation Leadership Scale (ILS, 48) on the subscales proactive, supportive, knowledgeable and perseverant leadership (staff and leadership versions). Measures were administered online using Enterprise Feedback Suite (49) and in local languages (translation approach in Supplement B). To account for the sequential REVERSE IPC implementation, the ORIC was administered at baseline, three, six, and ten months into implementation. The CSAT was administered at three, six, and ten months into implementation, and the ILS at ten months. Local REVERSE staff disseminated surveys among individuals involved in REVERSE IPC implementation.

Due to the lack of an existing, validated tool, we collaborated with REVERSE IPC researchers to self-develop a complexity rating for REVERSE IPC intervention components. Table 2 specifies data collection, Supplement A details factors and outcomes.

Data preparation

Three researchers (B.A., K.B., L.Ca.) extracted data, whereafter , factors and outcomes were converted into a data type suitable for CNA using *calibration.* Calibration assigns each factor and outcome a value to pre-defined categories based on a set threshold. In CNA, the specific value of a factor after calibration is a *condition*. We used binary conditions for all data due to low sample size and expected fragmentation (i.e., only a small proportion of possible configurations are observed in the data). Based on theory, case knowledge, and visual data inspection, two researchers (C.J., L.Ca.) conducted calibration.

Factors and outcomes nomenclature, and calibration thresholds are displayed in Table 2. Supplement A contains calibration rationales.

[Table 2]

Data analysis

Descriptive data are reported as weighted means (number of respondents representing the weight) across hospitals and timepoints. Steps outlined by Whitaker et al. (34) were adapted to conduct CNA across all 24 REVERSE hospitals, each representing a case. Two researchers (C.J., L.Ca.) conducted the analyses using RStudio (4.4.2) and the packages cna version 3.6.2 (52), frscore version 0.4.1 (53), and QCApro version 1.1-2 (54). Codes are shared in Supplement C.

Factor refinement

Factors were refined as follows. First, we visually examined data distribution to ideate calibration thresholds. Additionally, the 'msc' routine was used to identify minimally sufficient conditions (msc, 37, 55) at varying fit thresholds. Factors were selected to be carried forward into the modeling phase if they belonged to mscs with coverage scores of ≥ .50 for either outcome (INITIATION or COOPERATIVE BEHAVIOR).

Main analysis

In implementation research, single conditions are rarely sufficient and necessary, but they may influence the outcome when combined (*configurations*). So-called *INUS conditions* are *Insufficient* but *Necessary* parts of a combination of conditions that itself is *Unnecessary* but *Sufficient* for the outcome (35, 56). The INUS conditions are labeled *difference-makers* when they are redundancy-free, i.e., do not contain parts that are not needed to cause the outcome (56). To examine difference-makers for INITIATION and COOPERATIVE BEHAVIOR, calibrated (binary, crisp-set) data was used to conduct CNA .

Two main fit measures are used for CNA model building: consistency and coverage (57). Consistency quantifies the degree to which a model accounts for the cases showing the outcome (precision). Coverage describes how well the model covers the cases with the

outcome. Both range from 0-1. We used consistency and coverage thresholds of 0.75, as in prior CNA studies (31, 58, 59). In the main analysis, we ordered the data in sequential layers to temporally distinguish ORIC_BASELINE from other conditions.

Secondary analysis

As there is no gold standard for representing longitudinal factors in CNA, main analysis was followed by secondary analyses to identify suitable methods for representing the multiple ORIC timepoints. We evaluated the impact of including ORIC in two alternative ways: (1) ORC change scores named ORICCHANGE (between baseline and implementation period ORIC levels increased or stayed high, or they decreased or stayed low), (2) ORICOVERALL, which is high if either ORIC_BASELINE *OR* ORIC_T1T3 are high.

Model selection

In CNA, Boolean models (*solutions*) are returned, in which the asterisk (*) means *AND* , i.e., all listed conditions must occur together, and a plus (+) indicates *OR* , i.e., any condition can produce the outcome. The necessity/sufficiency relationship between conditions and outcomes is expressed with the *implication operator (↔)* and quantified with consistency and coverage.

Multiple models may account for the outcome equally well, i.e., have same consistency/coverage, challenging the selection of a final model. This is defined as *model ambiguity*, and we utilized theoretical knowledge to inform which models could be ruled out. Further, we examined individual cases' configurations to make sense of models and assess which cases aligned or diverged from suggested solutions (Supplement F). Next to model ambiguity, inconclusive evidence, noisy data or too high fit thresholds may result in CNA output that returns various related or unrelated models (60). We addressed *overfitting* through fit-robustness testing (fr score, 60, more information in Supplement F).

For final model selection, we examined models from this fit-robustness analysis in descending order, considering theoretical and case knowledge. The model with the most promising scores, reflecting theoretical understanding, was chosen.

Results

Descriptive characteristics

Data are summarized in Table 3 and Supplement D. At baseline and during implementation, ORC was similar (4.02 and 4.00). The average complexity was 83.96 (range: 59 to 114), and an average of 81% of implementation strategies clearly matched barriers. The mean initiation score was 20.38 (range: 12 to 27). Hospitals' cooperative behavior scores ranged from 1 to 9 (mean = 5.29). Of 24 hospitals, 17 submitted all RITs (i.e., 5/5). Five hospitals provided four RITs, one sent three RITs, and one submitted a single RIT. After three RIT reminders, we pursued the analysis with all RITs received (109 in total).

[Table 3]

Main results: Coincidence Analysis

Data preparation

Implementation leadership could not be meaningfully calibrated, as most hospitals reported high or very high implementation leadership and the data lacked variation. Therefore, this factor was excluded, as it would have provided limited differentiation between hospitals with high initiation and cooperative behavior and those with low values. Supplement D contains calibrated and uncalibrated data.

Factor refinement

Details of factor refinement are specified in Supplement E. During data reduction (msc), one factor (CSAT) was dropped (Supplement G and H). The final analytical factor set included enhanced (randomization to implementation condition), complexity, match, ORIC, with the outcomes initiation and cooperative behavior.

Main Analysis

This section summarizes the main CNA findings.Analytic details are reported in Supplement E. To align with theory and our research questions, the interpretation was separated by the two outcomes (i.e., outcomes cannot influence each other). However, to

use CNA at higher capacity and remain aware of potential interactions, the analysis was conducted on both outcomes simultaneously.

Main initiation analysis. The analysis considering only conditions measured during implementation generated two models for initiation (Supplement E for details):

1. **ENHANCED*ORIC_T1T3**+complexity*MATCH+COMPLEXITY*match ↔INITIATION (consistency/coverage = 0.77/0.83, fr score [normalized] = 4 [1])
2. **COMPLEXITY*ORIC_T1T3**+complexity*MATCH+COMPLEXITY*match ↔INITIATION (consistency/coverage = 0.77/0.83, fr score [normalized] = 3 [0.75])

These similar models have one differing pathway (bold): whether high readiness is paired with randomization to the enhanced implementation condition of REVERSE, or with highly complex IPC implementation. The second pathway expresses that with low complexity strategies must be clearly matched to barriers. The third pathway is difficult to interpret, as it translates to needing poorly matched implementation strategies when complexity is high. As this pathway does not align with implementation principles, and the fit-robustness analysis indicated a relatively low fr-score for both models, secondary analysis was conducted.

Secondary initiation analysis. Adding ORC change scores resulted in identical models (replacing ORIC_T1T3 with ORICCHANGE). Hence, we analyzed the data considering ORICOVERALL (high ORC regardless of the timing). While this analysis initially yielded two contradictory models (see Supplement E), we relied on fit-robustness analysis to select the best fitting model from the secondary analysis (Table 4) that corresponded with the theoretical background of our research:

3. complexity*MATCH+COMPLEXITY*ORICOVERALL↔INITIATION (consistency/coverage = 0.80/1.00, fr score [normalized] = 27 [0.61])

This model expresses that either low complexity paired with highly matched implementation barriers and strategies, or high complexity combined with high ORC were decisive for initiation. It is the only model without the uninterpretable COMPLEXITY*match pathway. Further, its conditions are fully represented in the main analysis in which only ORC

during implementation was considered (1. and 2.). In the main analysis, however, fit indices and theoretical knowledge did not help selecting one of the two models. There is one pathway shared by the three models, complexity*MATCH, which has high practical relevance and is theoretically reasonable. The variation of the complexity factor quantifies the scope of REVERSE hospitals' IPC implementation and is therefore highly relevant to inform practice. Additionally, the selected model has high fit-robustness (fr score [normalized] = 27 [0.61]) and good fit (consistency/coverage = 0.8/1.0). Overall, the CNA findings accurately reflect our knowledge of the hospitals. Thus, we selected this model to explain initiation.

Main cooperative behavior analysis. This analysis resulted in one model that was difficult to interpret (Supplement F for details):

4. complexity + ORIC_T1T3*match + ENHANCED*oric_t1t3*MATCH↔ COOPERATIVEBEHAVIOR (consistency/coverage= 0.8/ 0.86, not represented in fit-robustness analysis)

Secondary cooperative behavior analysis. Adding ORICCHANGE reproduced the results from the main analysis. When using ORICOVERALL, one model was returned, which posed interpretation challenges. The fit-robustness analysis did not reveal any well-suited models (Supplement F). Neither fit indices, nor theoretical or case knowledge allowed selecting a final model from main or secondary analysis of cooperative behavior. This indicates that we likely did not capture the factors in our study that make a difference in the presence of cooperative behavior over the whole implementation span.

[Table 4]

Discussion

We leveraged CNA, a novel configurational comparative approach, to investigate factors influencing IPC implementation and the role of ORC across 24 European acute care hospitals. Two pathways influenced IPC implementation initiation, one of which was low change complexity paired with highly matched implementation barriers and strategies. In

case of high change complexity, our analysis identified that its combination with high ORC at baseline or during implementation resulted in IPC implementation initiation. Our findings indicate that high ORC was decisive for timely implementation initiation when paired with implementation of highly complex IPC practices, but we found no difference-making evidence for ORC when IPC complexity was low. Instead, clearly matched implementation barriers and strategies led to timely IPC implementation initiation in hospitals undertaking less complex change. The results for cooperative behavior were inconclusive, as neither theoretical knowledge nor analytical grounds allowed identifying difference-making conditions from the examined factors.

Our findings suggest that IPC implementation cannot be explained by a single factor, but that combinations of conditions foster initiation of IPC implementation. These combinations vary depending on the complexity of the implemented IPC components (e.g., hand hygiene, active surveillance). Hospitals achieved timely initiation of IPC implementation activities in two ways. First, when hospitals implemented complex IPC components that, e.g., require substantial behavior change and cross-hierarchical interprofessional collaboration, depend on advanced information technology and data infrastructure, demand changes to the physical environment, and are costly, then sites with high ORC initiated IPC implementation promptly. Second, for hospitals implementing less complex IPC components characterized by relatively simple behaviors, lower need for collaboration, and minor dependence on data infrastructure, the selection of implementation strategies adequately addressing local barriers led to timely IPC implementation initiation.

While the benefits of tailored strategies to local context seem intuitive, the synthesized evidence supporting tailoring effectiveness is small to moderate (62). Although randomization to basic vs. externally facilitated tailoring (ENHANCED condition) was not a difference-making condition, its absence in the model does not translate to irrelevance. Notably, the degree to which implementation strategies matched with identified barriers was part of a difference-maker, which belongs to the tailoring definition (62), hence, one tailoring element was identified as a difference-maker in REVERSE. Although beyond the scope of

our study, these findings may influence ongoing discussions about tailoring effectiveness by adding the dimension of intervention complexity to this debate (63-65).

This work addresses several gaps identified in prior ORC literature. We respond to measurement challenges by measuring ORC with the pragmatic, psychometrically strong ORIC (46), administered in local languages, at baseline, and during implementation (26). The misalignment between ORC concept definitions, theories, and measurement has long been criticized (24, 66). The ORIC (46) stems from the TORC, and its administration enabled theory-based ORC measurement and interpretation of findings. Further, CNA allowed linking ORC with proximal outcomes (initiation, cooperative behavior), which has been called for previously (24). We tested parts of the TORC and laid the groundwork for understanding the role of ORC in IPC implementation.

Mixed-methods investigations are central in implementation research, but they have been critiqued due to lacking integration of quantitative and qualitative data (67, 68). Using CNA facilitated this integration within one analysis, enabling us to use various data sources. Next to a theory-driven outcome selection, we employed a systematic, bottom-up a priori factor selection, thereby optimizing data collection and use of research resources. The opportunity for inductive factor selection and data reduction is a reported advantage of configurational analysis (55). Finally, applying a case-based method allowed contextualizing our findings using insights gathered through data collection and hospital collaboration. This helped to interpret outcomes, shape different iterations of our CNA, and establish an understanding of ORC's role in IPC implementation (57, 69).

Three hospitals showed the initiation model without high initiation scores. Two of these hospitals' initiation scores were close to the calibration thresholds, potentially explaining this misalignment. Despite our rigorous calibration process, we leveraged CNA's advantage of interpreting the results at the case level. Anecdotal case knowledge facilitated the reasoning about why initiation in these hospitals was low, although the necessary and/or sufficient conditions were present.

The selected initiation model stems from secondary analysis (complexity*MATCH+COMPLEXITY*ORICOVERALL↔INITIATION). It addresses theoretical limitations of initial models as it does not contain pathways that do not resonate with theory and practice, and it contains pathways shared by both models from the main analysis. Integrating complexity in the reasoning about IPC implementation is highly relevant to inform practice. The complexity factor reflects the scale at which hospitals implemented REVERSE IPC, as hospitals chose the bundle components based on local conditions. It is important, in our assessment of the role of ORC, to integrate a complexity perspective, as "the content of change matters, not just the context of change" (21, p. 218). Further, complexity has been reported to influence motivation, which forms ORC (26).

Practice Implications

Our results also have practical implications. They indicate that hospitals implementing highly complex IPC practices must be ready for change to initiate implementation. It is therefore advisable to first assess complexity. While measures for intervention complexity are scarce (70), researchers may use or adapt the Intervention Delivery Complexity Tool, consisting of six domains (e.g., workflows, setting-dependency) to measure complexity (71). For implementers working in acute care settings and planning to implement more complex IPC practices, establishing a solid level of ORC seems warranted – among others, to ensure timely implementation initiation, including, e.g., early goal setting and scope definition, or alignment of timelines (Supplement A). Efforts to establish and maintain adequate ORC levels can be resource-intensive (26) and require long-term investment, among others in operational data streams that support measuring and monitoring ORC over time.

Besides the already mentioned ORC measures, often developed for research, other, more extensive frameworks can generate ORC data in practicebased settings. Gabutti et al. (72), identified various domains relevant to assess ORC within hospitals. Further, the Practical, Robust Implementation and Sustainability Model for Integrating Research Findings into Practice (73) considers ORC evaluations across top leadership, middle management, and frontline staff. If such assessments yield low ORC, pursuing efforts to build trust,

participatory leadership, and supportive organizational culture, all of which have been reported to impact ORC (24, 74-76), may enhance ORC. While there is limited guidance on concrete actions required to develop ORC, Watson et al. (77) outline an implementation mapping methodology for identifying actionable implementation strategies to build and enhance ORC.

Implementers may continue implementation without prioritizing ORC when the changes implemented are anticipated to be simpler. Then, organizations benefit from a thorough analysis of *how* and *why* potential implementation strategies might work, by prospectively identifying local determinants and investigating mechanisms behind strategies chosen to address these (26, 30)Tools are available to inform this process. For example, in complex implementation endeavors, structured but pragmatic approaches to selecting and tailoring implementation strategies can guide matching strategies to local determinants engaging relevant stakeholders (78-80).

Limitations

This research is subject to limitations. First, CNA is an exploratory, case-based approach and only allows for generalization of findings to similar contexts. Research in contexts different from European acute care is needed to validate our findings, e.g., in low-income countries or primary care. Moreover, capturing CNA data comes with challenges, as the method identifies necessary and/or sufficient conditions among included factors from available data sources, which rarely represent all building blocks of the underlying theory (Figure 1). Eventually, rigorous factor selection and operationalization processes, essential to ensure data collection feasibility, may have eliminated relevant TORC factors to explain cooperative behavior, potentially contributing to the inconclusive findings. Outcome selection and operationalization was challenging. The TORC lacks guidance on *how to understand* initiation and cooperative behavior in the implementation context and does not explain core components of these outcomes. We addressed this challenge by creating composite indices for initiation and cooperative behavior from qualitative RIT data, with differing weights of components contributing to these indices according to the conceptual background of our

study (39, 45). The validity and robustness of this procedure were not assessed, which we recognize as another limitation. The inconclusive findings on cooperative behavior may indicate opportunities to refine the measurement approach. A concrete conceptualization of ORC outcomes is needed to empirically test the TORC. While initiation and cooperative behavior are defined differently depending on the implemented change, basic principles for their conceptualization and operationalization might strengthen future research. We were also unable to analyze outcome chains, a unique feature of CNA, as the TORC does not state how outcomes influence each other. Similarly, we did not explore relationships between ORC determinants, due to the lacking theoretical basis for such analyses.

Further, we were unable to integrate implementation leadership in the CNA due to low variation in mostly high values across hospitals. Additionally, further REVERSE activities alluded to leadership as an area where staff exerted caution in information sharing, indicating potentially inflated ratings. While questions about sensitive topics, such as leadership, are at risk of social desirability bias and may misrepresent reality (81), leadership behaviors have been demonstrated highly influential in IPC implementation (82). For example, successful leaders assist in overcoming implementation barriers for HAI prevention (83) and create a change culture that fosters implementation (11). Considering leadership in our analysis may have provided valuable insights. To overcome these difficulties, methods for unbiased leadership assessments, e.g., through observations or administrative data, or trust-building strategies between survey respondents or interviewees and researchers, could be examined.

Response rates to the quantitative measures were partially low and varied considerably between sites. This hindered us in generating separate CSAT and ORIC factors for each timepoint, leading to an aggregation of the ORIC and CSAT data across three timepoints, resulting in a single ORC and sustainability factor. This also prevented testing of sequential factor relationships. While we organized our data into sequential layers and considered ORC change scores, we acknowledge that there is no gold standard to handle longitudinally measured conditions in CNA. Moreover, an in-depth analysis of qualitative hospital data was out of scope for this work, and a contextualization of CNA data depended

on a more informal, anecdotal understanding of local hospital conditions. Considering such an in-depth analysis would have allowed a more fine-grained interpretation of our findings.

Finally, our research represents only an initial spark toward uncovering the role of ORC in IPC implementation, as we did not examine system-level factors influencing acute care in the four countries studied. For example, we lacked conditions representing the differences between national healthcare systems. Future ORC research may investigate how acute care settings can be better equipped to navigate change implementation considering the ever-changing, increasingly difficult global situation that intensifies HAI-related challenges, like aging populations, pandemics, healthcare staff shortages, and political uncertainty (8, 84). Ideally, these examinations would triangulate different data streams to inform ORC assessments, such as validated quantitative tools, qualitative methods, and administrative data. This facilitates a comprehensive understanding of local conditions – including ORC – potentially influencing IPC implementation and HAI prevention.

Conclusions

To investigate implementation of HAI prevention measures, we tested *under which conditions* ORC matters for IPC implementation initiation and cooperative behavior. Using CNA, we found that high ORC levels are necessary and sufficient for IPC implementation initiation, but only if the change is of high complexity. This study exemplifies how configurational analysis and rigorous ORC measurement can inform future practice. While IPC implementation complexity may suggest directions for resource allocation (i.e., to building ORC or selecting appropriate strategies to address local barriers), further research with larger study samples in different contexts is needed to validate these results.

List of abbreviations

CNA	Coincidence Analysis
CSAT	Clinical Sustainability Assessment Tool
ESI	Evidence-supported Intervention
HAI	Healthcare-associated Infection
IPC	Infection Prevention and Control
ILS	Implementation Leadership Scale
MSC	Minimally Sufficient Condition
ORC	Organizational Readiness for Change
ORIC	Organizational Readiness for Implementing Change
PPS	Point Prevalence Survey
REVERSE	pREVention and management tools for rEducing antibiotic Resistance in high prevalence Settings
RIT	REVERSE Implementation Tool
TORC	Theory of Organizational Readiness for Change

Declarations

Ethics approval and consent to participate

REVERSE has received ethical approval from the Canton of Zurich (AO_2021-00078), and from 24 REVERSE hospitals' ethics committees. Individual survey respondents gave electronic consent.

Consent for publication

Not applicable

Availability of data and materials

All data used for this study are included in this published article and its supplementary information files.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

B.A., L.Ca., and L.Cl. conceptualized the study. B.A., K.B., and L.Ca. were involved in data collection. C.J. and L.Ca. conducted the analysis. L.Ca. and L.Cl. drafted and finalized the manuscript. All authors provided critical feedback on the manuscript.

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REVERSE Study Group:

Bianca Albers, Anna Rosa Andritsos, Ana-Maria Anghel, Alberto Antonelli, Athanasios Antoniou, Eirini Apostolidi, Alejandro Araujo Ameijeiras, Alessandra Bandera, Lorenzo Biasoli, Teresa Bini, Victoria Bîrluțiu, Kathrin Blum, Greet Boland, Laura Caci, Eva Cappelli, Yehuda Carmeli, Elena Carrara, Anna Celotti, Eirini Christaki, Lauren Clack, Marco Coppi, George Daikos, Anca Damalan, Daniele Fasan, Maurizio Moreno Fattori, María Fernández-Billón Castrillo, Anca Georgescua, Valeriu Gheorghita, Valérie Goldstein, Sotiria Grigoropoulou, Cosmina Gringaras, Silvia Guerriero, Silvia Guillen Climent, Stephan

Harbarth, Carlota Hidalgo López, Juan Pablo Horcajada Gallego, Raluca-Maria Hrișcă, Adriana Hristea, Diana-Gabriela Iacob, Mariana Iacobescu, Magda Ialonardi, Bogdan-Daniel Jerdea, Anastasia Kiousi, Jan Kluytmans, Flora V. Kontopidou, Elena Kovlakidi, Malvina Lada, Salvador López Cárdenas, Davide Mangioni, Giulia Marchetti, Symeon Metallidis, Esperanza Merino, Lacramioara Andreea Mohorea, María del Dulce Nombre Montaner Quiroga, Maria Milagro Montero, Marina Murillo Pineda, Rita Murri, Mihai Negrea, Cristina Negulescu, Aude Nguyen, Cristian-Mihail Niculae, Tudor Rareș Olariu, María Teresa Pérez Rodríguez, Maria Pirounaki, Jack Pollard, Corina Pop, Koen Pouwels, Pilar Retamar Gentil, Francesco Rizzolo, Julie Robotham, Jesús Rodríguez Baño, Friederike Roeder, Estrella Rojo Molinero, Gian Maria Rossolini, Rafael Ruiz Montero, Natasha Salant, Inmaculada Salcedo, María Sánchez Valero, Vered Schechner, Elisa Sicuri, Nikolaos Sipsas, Anna Skiada, Ashlesha Sonpar, Giacomo Stroffolini, Manuel Suárez Vázquez, Evelina Tacconelli, Labros Tampakas, Maela Tebon, Sara Tedeschi, Andrea Tedesco, Carlo Torti, Maria Tsakona, Stavroula Tsiara, Sotirios Tsiodras, Ourania Tsompikou, Eline Verhagen, Pierluigi Viale, Daisy Vries, Kristina Zefi, Sofia Zerva, Zheng (Jessie) Zhang, Walter Zingg, Panagiotis Zisimopoulos, Nadia Zuabi García.

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Table 1. Intervention components of the REVERSE Infection Prevention and Control bundle, adapted from Albers et al. (39).

Intervention component	Description
Hand hygiene	Enhanced standards for hand hygiene, based on the World Health Organization's "5 moments of hand hygiene"
Contact precautions	Enhanced standards for contact precautions, containing the use of personal protective equipment, limited patient transport and movement, enhanced cleaning of patient rooms, and separation of patients
Isolation and cohorting	Guidance on correct placement of patients colonized or infected with a multidrug-resistant organism, isolation or cohorting of these patients, and using staff solely dedicated to these patients
Active surveillance	Organization of a system for systematic patient screening for multidrug-resistant organisms, on admission and periodically
Environmental hygiene	Enhanced standards for environmental cleaning procedures in the patient zone
Outbreak management	Development of protocols and processes to use after the detection of outbreaks with multidrug-resistant organisms

Table 2. Overview of factor and outcome definitions, data collection methods and calibration methods.

Factor/outcome	Data collection methods and roles providing data	Calibrated factor, Boolean expression (n and % of hospitals assigned), and definition			Calibration threshold[9]
Outcomes					

Cooperative behavior: behaviors are executed that indicate active collaboration with IPC implementation	- **Method**: Mixed methods
	- **Measure**: Weighted sum based on
	  ○ Percentage of reported implementation strategies falling under "Develop Stakeholder Interrelationships"[1]
	  ○ Representation of ward staff roles in implementation team
	  ○ Representation of ward staff roles in engaged stakeholders external to the implementation team
	- **Data source**: REVERSE Implementation Tools (RIT) of first implementation year
		COOPERATIVE BEHAVIOR	1 (n = 14, 58.33%)	High cooperative behavior	Above natural gap in the data, which is close to median, ≥ 5

		cooperative behavior	0 (n = 10, 41.67%)	Low cooperative behavior	Below natural gap in the data, which is close to median, < 5

Initiation: IPC implementation is set up soon after kick-off, and activities are started in a timely manner	- **Method**: Mixed methods
	- **Measure**: Weighted sum based on
	  ○ On-time submission of RIT
	  ○ Early goal identification prior to first RIT submission during Organizational Readiness for Implementing Change[2] (ORIC) baseline assessment
	  ○ Goal identified according to SMART[3] criteria
	  ○ Number of components of the Infection Prevention and Control (IPC) bundle planned for implementation
	  ○ Defined number of hospital wards for IPC implementation
	- **Data source**: RITs of first implementation quarter
		INITIATION	1 (n = 12, 50%)	Timely initiation	Above median, ≥ 21.5

		initiation	0 (n = 12, 50%)	Lagged initiation	Below median, < 21.5
Factors					
Complexity: set of IPC components entails behavior change, interprofessional collaboration across hierarchies, and depends on organizational infrastructure and resources	- **Method**: Quantitative - **Measure**: IPC complexity rating tool co-developed with the REVERSE IPC research team[4]. - **Data source**: Each selected IPC component indicated in the RITs during the first implementation year was rated by the REVERSE IPC research team based on complexity.	COMPLEXITY	1 (n = 15, 62.5%)	Change implemented is of high complexity	Above average complexity of three components (the number recommended for implementation in 1st year), ≥ 84
		complexity	0 (n = 9, 37.5%)	Change implemented is of low complexity	Below average complexity of three components (the number recommended for

					implementation in 1st year), < 84
Implementation leadership: IPC leadership is proactive, knowledgeable, supportive and perseverant	- **Method**: Quantitative - **Measure**: Implementation Leadership Scale (ILS[5]) - **Data source**: Online survey administered with staff involved in implementation activities, including the implementation team ten months into implementation, and with IPC leadership, approximately one year into implementation	*We were not able to calibrate ILS scores due to data distribution (also see results section)*			
Implementation strategies used (1): Selected implementation strategies match identified barriers	- **Method**: Qualitative - **Measure and data source**: Based on an assessment of whether the barriers identified by the implementation team in the RITs of the first implementation year matched the implementation strategies used.	MATCH	1 (n = 15, 62.5%)	Barrier-strategy pairs clearly match to a higher degree	Above median, ≥ 88%
		match	0 (n = 9, 37.5%)	Barrier-strategy pairs clearly match to a lower degree	Below median, < 88%
Implementation strategies used (2): ENHANCED vs. BASIC tailoring condition	Based on a-priori trial randomization of implementation conditions[6]	ENHANCED	1 (n = 12, 50%)	Randomized to facilitated (ENHANCED) tailoring	Groups built based on randomization
		enhanced	0 (n = 12, 50%)	Randomized BASIC implementation	
Organizational readiness for change (ORC) – **baseline**: staff is behaviorally and psychologically prepared for IPC implementation prior to its implementation	- **Method**: Quantitative - **Measure**: ORIC[2] - **Data source**: Online survey administered with implementation teams four to six weeks after implementation kick-off	ORIC baseline	1 (n = 14, 58.33%)	High ORC level at baseline	Indicates agreement on the scale, ≥4
		oric baseline	0 (n = 10, 41.67%)	Low or neutral ORC level at baseline	Indicates neutrality or disagreement on the scale, <4
ORC during implementation: staff is behaviorally and psychologically prepared for IPC implementation during the active implementation period	- **Method**: Quantitative - **Measure**: ORIC[2] - **Data source**: Online survey administered with staff involved in implementation activities, including the implementation teams, at three, six, and ten months into implementation	ORICT1T3[7]	1 (n = 11, 45.83%)	High ORC level during implementation	Indicates agreement on the scale, ≥4
		orict1t3	0 (n = 13, 54.17%)	Low or neutral ORC level during implementation	Indicates neutrality or disagreement on the scale, <4
Sustainability: Perception of sustainable IPC implementation	- **Method**: Quantitative - **Measure**: Clinical Sustainability Assessment Tool (CSAT[8])	CSAT	1 (n = 13, 54.17%)	Higher sustainability	Above median, ≥5.36

	- **Data source**: online survey administered with staff involved in implementation activities, including the implementation team, at three, six, and ten months into implementation	csat	0 (n = 11, 45.83%)	Lower sustainability	Below median, < 5.36

Note. Boolean Algebra notation: upper case letters factor presence, lower-case letters factor absence; Percentages are rounded to two digits; ORIC and CSAT data were aggregated, i.e., the timepoints were merged into one data point; [1]based on Powell et al. (50) and Waltz et al. (51); [2] Organizational Readiness for Implementing Change (46), based on the Theory of Organizational Readiness for Change (22); [3]Specific, Measurable, Attainable, Relevant/Realistic, Time-bound; [4] Details in Supplement A; [5] Implementation leadership scale, staff and leadership versions (48); [6] Randomization to BASIC or ENHANCED, see methods; [7]T1T3 = timepoints 1, 2, 3, indicating data aggregation across three, six and ten months of implementation; Clinical Sustainability Assessment Tool (47); [9]Values on the threshold get assigned to the upper category.

Table 3. Descriptive outcome and factor data of the 24 hospitals.

	Mean across hospitals	Range across hospitals	Possible range of factor/outcome	Total number of individual responses (range across hospitals)
Outcomes				
Initiation score	20.38	12–27	10–29	NA
Cooperative behavior score	5.29	1–9	0–9	NA
Factors				
ORC baseline (ORIC score)	4.02	2.75–4.92	Scale from 1 (“Disagree”) to 5 (“Agree”), higher scores indicating higher ORC	78 (1–6)
ORC during implementation (ORIC score)	4.00	2.95–4.70	Scale from 1 (“Disagree”) to 5 (“Agree”)	805 (1–130)
Sustainability (CSAT score)	5.27	4.75–6.31	Scale from 1 (“To little or no extent”) to 7 (“To a very great extent”)	664 (1–77)
Implementation Leadership, staff (ILS score)	3.09	2.62–3.74	Scale from 0 (“Not at all”) to 4 (“Very great extent”)	241 (1–38)
Implementation leadership, leaders (ILS score)	3.31 (based on n=22, missing data from two hospitals)	1.83–4	Scale from 0 (“Not at all”) to 4 (“Very great extent”)	33 (1–5)
Implementation strategy-barrier matches	81% of strategies clearly matching barriers	0–100%	0–100%	338 strategy-barrier pairs assessed
Complexity score	83.96	59–114	18 (only least complex component implemented)–168 (all components implemented)	NA

Note. Quantitative data was provided for all data collection waves by 21 hospitals. Two hospitals sent data for two out of three timepoints, and one hospital collected data for one timepoint. Only complete responses to the quantitative questionnaires were retrieved to calculate hospital means. Data from all 24 hospitals are used unless otherwise indicated. Data are reported as weighted means. Initiation and cooperative behavior data are calculated as mean scores from weighted sums (24 hospitals). Data for organizational readiness for implementing change (ORIC) and the Clinical Sustainability Assessment Tool (CSAT) are reported across the three-, six- and ten-month timepoints. For the CSAT, ORIC, and Implementation Leadership Scale (ILS), higher values indicate higher sustainability, organizational readiness for change (ORC), and implementation leadership, respectively. Higher initiation scores indicate higher degree of initiation of REVERSE IPC implementation, and higher cooperative behavior scores indicate higher degree of cooperative behavior in REVERSE IPC implementation. Details of factors and outcomes are reported in Supplement A.

Table 4. Visualization of pathways in the final model for INITIATION.

ID	ENHANCED	ORICOVERALL	COMPLEXITY	MATCH	INITIATION
B	1	0	0	1	**1**
C	1	1	1	0	**1**
D	0	1	1	0	**1**
H	1	1	1	1	**1**

J	0	1	1	1	**1**
M	0	1	1	1	**1**
N	1	1	0	1	**1**
R	1	1	1	1	**1**
S	1	1	1	1	**1**
U	0	1	0	1	**1**
W	0	1	1	0	**1**
X	1	1	1	1	**1**
A	0	0	0	0	**0**
E	1	0	1	1	**0**
F	0	1	1	1	**0**
G	0	0	0	0	**0**
I	1	0	1	0	**0**
K	1	0	1	1	**0**
L	0	0	0	0	**0**
O	1	1	0	0	**0**
P	0	1	0	1	**0**
Q	0	1	0	0	**0**
T	0	1	1	1	**0**
V	1	0	1	1	**0**

Model: complexity*MATCH + COMPLEXITY*ORICOVERALL ↔ INITIATION

Purple pathway: COMPLEXITY*ORICOVERALL

Blue pathway: complexity*MATCH

Number of cases expressing the model (at least one pathway): 15

Number of cases with high initiation: 12

Consistency: 12/15 = 0.8 (number of cases with both the model and the outcome divided by number of cases that express the model)
Coverage: 12/12 = 1.0 (number of cases that express both the model and the outcome divided by number of cases that express the outcome)