

# Understanding the role of complexity in bottom-up healthcare innovations: a multiple case study using the NASSS-CAT tool

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## Research Article

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# Abstract

**Background:** New digital technology presents new challenges to healthcare on multiple levels. There are calls for further research embracing the complex factors related to digital innovations in complex healthcare settings in order to bridge the gap in moving from linear, logistic research to embracing and testing the concept of complexity. The aim was to explore the role of complexity in bottom-up innovations within public healthcare in a Swedish region.

**Methods:** Four bottom-up innovators identified complexities in their innovations using the NASSS framework with its seven domains (condition, technology, value proposition, adopters, organisations, wider system and embedding, and adaption over time); the related Complexity Assessment Tool (CAT); and Constant Comparative Analysis (CCA), in collaboration with the Innovation Platform in the Region Västra Götaland in Sweden.

**Results:** An initiated understanding of the complexity relating to the illness addressed in the innovation is of great importance as a starting point. Value proposition needs to be clearly described early in the process, to enable understanding costs and outcome. If regional support only allows regional use, not national spread, there will be no dissemination and the innovations risk failing after the initial project phase.

**Conclusions:** Using a validated tool early in the process of innovation is helpful but requires profound knowledge about complexity and the intended system for implementation. Finding and defining complexity does not solve the issues, but will increase possibilities of success if the right competence is available for support.

**Trial registration:** n/a

## Background

New innovative technology

For organisations, the ability to innovate provides major competitive advantages. Effectiveness and efficiency can be enhanced when organisations compete for developing the “best innovation”. Organisations use innovations to respond to the needs in healthcare to improve organisational efficiency and to be economically viable (1) with the goal of achieving personalized and evidence-based care (2). However, developing new technologies comes with significant challenges, e.g., with the slow uptake of “disruptive” technologies (3, 4). For example, digitalisation has not been able to resolve fundamental problems related to quality, safety, and cost (5).

Studies about complexity show how technology projects in healthcare have a high rate of failure, particularly, large and complex projects, which seldom provide the anticipated results (6–8). It is not believed that projects fail due to a poor quality of ideas, but rather due to a lack of managing and

understanding of the innovation process in the organisation in which the innovation is supposed to function. Systems seek stability, which often presents itself as a desire to continue doing things as they have always been done (9). Moreover, it has been recognized that, often: a) uncertainty exists regarding resources and financing for the innovation, and b) there is a lack of a defined framework for innovation in the organisation. Thus, the gap between usefulness in a clinical context and technology development needs to be bridged. If not, there is a risk that new technology further increases the complexity, rather than actually supporting the needs and demands for an improved healthcare system (5).

### Bottom-up innovations in healthcare

Bottom-up innovations are innovations for service delivery that have been developed “from the ground up”, often focused on preventive patient-centred care, driven forward by small interdisciplinary groups of professionals and patients. They might not be captured by existing metrics, thus being “invisible” to senior management and policy makers (1).

Several theoretical approaches have been made to provide a conceptual framework to implement new practices in healthcare and provide policy makers with informed theory-based approaches: behavioural theories in combination with technology and an understanding of healthcare delivery systems (2); the Triple C model (Consultation, Collaboration and Consolidation) for sustainability of interventions (4); and the Normalisation Process Theory (1), just to name a few.

External partner institutions and academic involvement in facilitating healthcare redesign is becoming more common and has both benefits and pitfalls, depending on the mix of expertise and skill. Overall, accountability and mutually respectful relationships are fundamental for the collaborative, sustainable and successful completion of clinical research projects (3). To succeed in innovation requires sensitivity to emergence and unpredictability in complex systems.

### The role of complexity in bottom-up healthcare innovations

Healthcare can, like other systems, be described somewhere along a continuum, ranging from simple (predictable, with few components) to complicated (predictable but with more interacting components), and to complex (dynamic and unpredictable, the whole being more than its constituent parts) (5). Complex systems are defined by: a) intricate inter-twined processes, b) interconnectivity between systems, c) interconnectivity between levels within systems, and d) between actors and elements, giving complex systems other properties than less complex systems (6). A concept of stepwise linear cause-and-effect is not sufficient when studying complex systems that evolve in ways that are impossible to predict. It is therefore more relevant to use the knowledge of complex systems when understanding and studying health services (10).

Capability among individual agents in a complex system, that is, “the extent to which an individual can adapt to change, generate new knowledge, and continue to improve their performance” (11), can be supported by minimum specifications (simple rules to guide behaviour) and feedback loops, letting

individuals gradually upgrade their internalized rules through experience. Relevant feedback on performance is crucial to enable continuous learning and improvement at all levels of a healthcare system, from the level of individual patients to organizational management and policy levels, potentially enabled by the use of new technologies (5, 12–14). There are calls for further research that embraces the complex factors related to innovations in healthcare settings, and that intend to bridge the gap between linear research and testing the concept of complexity (7, 8).

## Aim

The aim was to retrospectively explore and understand the role of complexity in four bottom-up healthcare innovations by using the long version of the NASSS-CAT tool.

## Method

Complexities in the innovation process were explored in a multiple case study including four bottom-up innovations developed in the Region Västra Götaland (VGR). The study followed an iterative process, including analyses, discussions, and seminars (see Fig. 1). The NASSS (Nonadaptation, Abandonment, and challenges to Scale-up, Spread, and Sustainability) framework for theorising and evaluating healthcare technologies was applied, using the NASSS-CAT tool long version, for the analysis (10).

While using the NASSS-CAT in each of the four cases, the innovators had discussions about how to interpret the questions in the seven domains. An additional method was chosen, constant comparative analysis (CCA), as it is appropriate in collaborative projects to facilitate and identify agreements and disagreements (11, 12). By using CCA, agreement and disagreement statements within the group were made, e.g., “negotiations” of the definition/interpretation of specific questions in the NASSS-CAT long tool (13, 15) (see Additional file 2).

A summary of the analysed complexities, as well as further suggestions for how to use the framework for bottom-up innovations, were formulated by the four innovators and are presented in the results and discussion sections.

## The history of the development of the NASSS framework and the NASSS-CAT tools

It has been acknowledged that failures in new healthcare technology can seldom be quickly solved with technology only. The interaction between individuals, organisations, technology, and policy is crucial for understanding why, or why not, new technology is sustainably adopted within health and social care (10, 16). By identifying key domains through systematic hermeneutic reviewing and using empirical case studies of technology implementation to elaborate and explicate the domains further, the NASSS-framework was created and tested with cases also originating from the VGR (17). The NASSS-framework was intended to be used to predict and evaluate the success of implementing a technology embedded in its socio-technical context. Complexity was illuminated by applying sub-questions to 6 domains: 1) the condition, 2) the technology, 3) the value proposition, 4) the adopter system (e.g., staff and patients), 5)

the health or care organisation(s), and 6) the wider context. In the seventh domain, the existence of complexities as they emerge over time are addressed.

However, the developer of the NASSS-framework adapted the tool further to make it easier to complete self-assessments of the complexity in healthcare innovation projects by incorporating the Complexity Assessment Tool (CAT) into NASSS. To cite Maylor et al.: *"The greater the complexity posed by a project, the lower the chance that any successful outcome, let alone an innovative one, will be achieved"* (18), p46. This statement served as the basis for developing the CAT. Maylor et al. (19) found it necessary to study not only complexity, but different *kinds* of complexities in order to meaningfully assess, describe, and address complexity in projects. They divided complexity into: 1) structural complexity, 2) socio-political complexity, and 3) emergent complexity. *Structural* complexity is associated with the level of interdependence between people, stakeholders, scope, size, and pace of the project. *Socio-political* complexity is about the politics, agendas, and perceived importance of the project that is being studied, present within the project and imposed by external stakeholders. *Emergent* complexity is associated with uncertainty and change, typically in technology, requirements, scope, or resources. Changes in socio-political and structural complexity cause challenges related to the emergent complexity. The CAT tool was merged with NASSS to form the NASSS-CAT tool (20).

NASSS-CAT is a complexity self-assessment tool divided into two parts. Part one focuses on identifying three different types of complexities (structural, socio-political and emergent) in the six NASSS-domains (condition, technology, value proposition, adopter system, organisation and wider context). Part two is an implementation plan with headers supporting clarification of project properties and actions to address the complexity of a project (e.g., vision, leadership, stakeholders, governance, cross-sector relationships, getting started, empowering the front line, measuring progress, high-level timeline, risks and challenges, and summary). The NASSS-CAT is available in four different versions: a short (introductory); a long (for preliminary planning); a project version (for monitoring); and an interview version (for evaluation or research) (20).

## Setting and process

The VGR is a region on the western coast of Sweden with a total population of 1.7 million. The Innovation Platform (IPF) is the regional support resource for innovations in healthcare. The mission of the IPF is to contribute to a sustainable innovation system that promotes innovation in healthcare and ensures that collaboration between academia and business fulfils the needs of patients and the healthcare system. The IPF provides innovation projects with coaching, help with legal services, and facilitates co-operation with other units, such as the regional IT department.

The four authors, all bottom-up innovators, are e-Health pioneers and clinical researchers in the VGR, striving to improve care for their targeted patient groups. The authors came together through a network meeting initiated by one of the innovators in 2019 and realised how their separate innovations had been hindered by similar factors, such as organisational lack of knowledge and awareness, and lack of

experience regarding the successful development, testing, implementation and maintenance of digital bottom-up innovations.

The four bottom-up innovations

Each innovation is presented below and in Additional file 1.

## **Case 1**

D-Foot

Prevention of diabetic foot ulcers (DFU) includes: a) an annual foot examination, b) intervention with podiatry, access to appropriate footwear for patients at risk, and c) treatment in a multidisciplinary team for patients with active DFU (21–23). However, 25% of people diagnosed with diabetes are not examined in a structured manner, and, therefore, interventions such as access to podiatry services, adequate footwear, or care in multidisciplinary teams are delayed or absent (24).

D-Foot was developed as an easy-to use digital tool for foot examination of persons diagnosed with diabetes. The D-Foot was primarily intended for prosthetics and orthotics specialist care (25) and by further improvement to be used by other healthcare professionals. The intention was to implement the D-Foot nationally for all patients in Sweden ( $n = 500\ 000$ ) visiting a department of prosthetics and orthotics with the purpose of being provided with therapeutic footwear. With a structured annual foot assessment, supported with tools such as the D-Foot, early prevention leads to improved quality of life (26, 27) and cost savings (15, 28).

## **Case 2**

MoodMapper

Bipolar disorder is a group of chronic, affective disorders in which patients experience episodes of either manic or hypomanic states and/or periods of depression. The transition from a stable state to periods of illness is marked by behavioural changes such as an increase or decrease in psychomotor activity, social engagement, and disturbed sleeping patterns. Early detection of behavioural changes is of the utmost importance in the successful treatment of bipolar disorder.

The aim of this innovation was to determine whether smartphone usage data are a reliable source for studying changes in the digital behavioural patterns of individuals with bipolar disorder through exploring correlations between different parameters of smartphone usage data.

The smartphone application MoodMapper allows for real-time data to be collected around the clock through the internal sensors and processors of the smartphone.

This study supports the hypothesis that smartphone usage data can reveal unique digital patterns that open up the possibility for the patient and their doctor to study the personalized profile, reflecting the

patient's stable state.

### **Case 3**

#### Digi-Do

Radiation Therapy (RT) is a common treatment after breast cancer surgery. The high-tech environment and unfamiliar nature of RT can affect the patient's experience of the treatment. Misconceptions or lack of knowledge about RT processes can increase levels of anxiety and enhance feelings of being unprepared at the beginning of the treatment. Moreover, the waiting time is often quite long.

The Digi-Do tool consists of two separate mobile applications: a guided digital tour of the RT-department, in which the patient can familiarise herself with by using VR-glasses; and one with additional information, including Q&As, practical information and short animated films about the RT process. Both apps have been developed in co-design with patients and staff. The primary aim for the researcher/innovator was to evaluate whether a digital information tool with VR-technology and preparatory information can decrease distress as well as enhance the self-efficacy and health literacy of patients affected by breast cancer before, during, and after RT. A secondary aim was to explore whether the digital information tool increases patient flow while maintaining or improving the quality of care (29).

### **Case 4**

#### POC Dashboard

The Department for Schizophrenia Spectrum Disorders at Sahlgrenska University Hospital delivers specialized care for people with psychotic disorders in the metropolitan Gothenburg area (population of approximately 600,000 people) in Sweden. Schizophrenia is the most common diagnosis among the approximately 3000 patients who receive care at the Department's 7 outpatient units. About 20% of these are also in need of acute inpatient care at one of the Department's 4 wards each year.

In an ambition to support patient co-production of health, a digital dashboard was developed, to be jointly reviewed at the point of care by patients and case managers/psychiatrists to support evaluation and planning, outcomes questionnaires, and patients' care plans (13). The Dashboard was developed between 2016 and 2018 and was piloted at 2 outpatient units with approximately 400 patients for 18 months. The dashboard is one of several connected applications and displays to visualize data fed by multiple systems to support, e.g., planning, management, and triage, and includes a unit-level overview of quality indicators to identify patients at risk.

The four innovators decided to identify both the unique and shared complexities of their innovations by adapting the NASSS-framework. Also, representatives from the IPF attended the same meeting, and, as the IPF was designated to improve the regional innovation processes, a collaboration was set up to share experiences, knowledge, and insights of how complexities needed to be identified and handled to improve successful innovations.

This study included several steps, Fig. 1:

1. Four bottom-up innovators had individually experienced complexities during their respective innovation processes from 2010–2019.
2. The four innovators started the multiple case study in January 2020 by learning how to use the NASSS framework.
3. The innovators identified complexities in their individual projects with the use of NASSS-CAT long tool (20) during 2020.
4. During > 30 meetings, the innovators identified, compared, and discussed similarities and differences regarding complexities in their respective innovations. A constant comparative analysis (CCA) was included in this process and is described in Additional file 2.
5. A seminar was held in April 2020 with one of the bottom-up innovators and the IPF, presenting the concept of complexity and the NASSS framework.
6. In October 2020, another workshop was held with the four innovators and staff members from the IPF to discuss the domains in NASSS, illustrated with examples from the four innovations projects. The participants from the IPF discussed and reflected the ways in which they had encountered complexity in their own work.
7. The authors were commissioned to write a Swedish report for the IPF, exploring and summarising the NASSS framework and complexity with examples from their own bottom-up innovations (30).
8. The insight from the whole process above was discussed and summarized by the four bottom-up innovators, as presented in this paper.

## Results

Using the CCA interpretations from multiple perspectives (cases), a shared understanding regarding how to interpret the questions in NASSS-CAT was established (Additional file 2). Thereafter, in this retrospective exploration of the role of complexity in four bottom-up healthcare innovations in a Swedish region, both similarities and differences emerged between the four cases (Additional file 1). Some of these findings were independent of the setting, while others were clearly related to the regional support structure and the climate for bottom-up innovations in the VGR.

The findings for each domain are described below, first, for all four cases with clarifying examples, complemented with short reflections from the workshop with IPF.

### Complexity Domain 1: The Illness or Condition

*The condition and issues related to complexities are described in domain 1.*

#### The four cases

Complexity in this domain was related to whether there was a clearly defined, time-restricted process of treatment, or whether the illness was chronic and involved other aspects than healthcare alone. Three

cases dealt with conditions or illnesses that were described as complex (D-Foot, MoodMapper, PoC Dashboard), and one as simple (Digi-Do).

MoodMapper and PoC Dashboard were directed towards severe mental illness. Both diagnoses are strongly connected with comorbidity and lifestyle-related conditions, and even though national guidelines exist, there is no simple pathway to treat or cure the conditions.

The third case (D-Foot) involved diabetes, also an illness defined as complex due to the patient being treated in various institutions and with several lifestyle factors influencing the outcome of the treatment.

Digi-Do was related to the treatment of breast cancer with curative intent. There are clearly defined pathways for treatment and evaluation. Due to this, it was considered as a non-complex diagnosis, even if a cancer diagnosis certainly can be experienced as being serious by the individual patient.

For all four patient groups included in present study, socioeconomic factors, lifestyle, and levels of health literacy might affect their condition and treatment.

### Reflections from the workshop

In the workshop, the participants realized that they were often quick to search for a solution for a specific diagnosis/condition, rather than considering whether the condition itself was complex. Problems can occur if the complexity is viewed only in relation to the specific innovation and not the illness itself. The participants might also acknowledge a condition changing from complex to simple, as deeper knowledge was obtained.

### Complexity Domain 2: The Technology (or other innovation)

*The existence of complexities in the technology/innovation is analysed in domain 2.*

### The four cases

Complexity in this domain was related to the actual technology, as well as to the supply chains for the innovation.

For the actual technology, similarities regarding complexities revolved around interdependencies with other IT-systems, ranging from local to regional and even national systems. The regional IT-department was viewed as being both a hindrance and a help. Even if the technology already existed (D-Foot), or if new software was developed to create a better overview of data in several existing systems (POC Dashboard), it was difficult to develop the innovation beyond the local settings. Regulations regarding software used as medical devices (31) overpowered the simple adaptations amended for different target groups. "Fireproof" walls exist between different versions of the regional information systems, all to do with ownership, budget, and management.

Fortunately, the Digi-Do app does not require any interaction with existing IT-systems. The MoodMapper app, on the other hand, is complex, as it aims to interact with both patients and healthcare staff, requiring interaction with medical electronic health records.

The need for supply chains involved both purchasing/procurement as well as clinical implementation; the latter involving questions regarding intellectual properties and ownership related to management and updates.

All cases had run into, or expected to run into, severe complexity when intending to launch their innovations. Regulations regarding funding and ownership made it difficult to implement a supply chain outside the local region (D-Foot), as each of Sweden's 21 regions have their own procurement processes. For all four cases, insurmountable problems arising late in the innovation process had not been addressed early enough, and it was clear that complexity regarding supply chains had not been accounted for when intending to expand from a local level to a regional or national one.

### Reflections from the workshop

The participants agreed that almost all innovations were generally complex in this domain, and that a shared IT platform was needed to overcome problems with interacting systems. They discussed how involving the end users at an early developmental stage might ease the innovation process.

### Complexity Domain 3: The Value Proposition (costs and benefits of the technology)

*In domain 3, complexities in relation to the value proposition are analysed.*

### The four cases

All four cases were explicit bottom-up innovations, arising from a need for improvement as expressed by patients and/or staff.

For Digi-Do, there was a defined regional vision for improving the process of radiotherapy, but it had not been specified how this should be addressed. It was difficult, bordering on impossible, to calculate a cost-benefit analysis for any of the four projects. This was admittedly most prominent for Digi-Do, which aims to turn the patients' meaningless waiting time into a meaningful preparation stage before radiotherapy. Soft values, such as reduced distress, heightened health literacy and self-efficacy, are difficult to both measure and put a price tag on, particularly as the intervention will most likely not affect the number of treatments required, or the survival rate of the users. However, a well-prepared and less anxious patient might pass through the treatment system quicker, and even though the treatment cost remains the same, the queues might be reduced.

For the other cases, it was difficult to define exactly where in the process the cost and value could be calculated. Early interventions in the treatment process (D-Foot) might require more resources within

primary care but result in less need of specialist care later on. Early detection of foot ulcers will definitely have increased value for patients living with diabetes.

In the cases (MoodMapper and POC Dashboard) that intend to prevent relapse in severe mental illness by coordinating data or even by asking patients to send in and react to data, these most likely reduce the need for hospital care when the innovations are used by outpatient clinics.

#### Reflections from the workshop

During the workshop, it was evident that the innovators considered the cost-benefit calculations and business plans to be difficult and almost uncomfortable to address. Health-economic analysis seemed to be urgently needed as part of the evaluation of innovation projects.

#### Complexity Domain 4: The Intended Adopters of The Innovation/Technology

*In domain 4, complexities arising from any possible users of the technology are described and analysed.*

#### The four cases

All four cases had implications requiring either a behavioural change for the patients, and/or a change in work routines for the staff.

For example, using the POC Dashboard an outpatient clinic made it easier for the staff to gain an overview of relevant patient data, thus saving time. The dashboard was experienced as a big improvement in their daily work. For the patients, the POC Dashboard was also well received, as the overview made it easier for them to see their own patterns of illness and treatment-related behaviour. The new routines were thereby seen as solely positive.

In contrast, D-Foot seemed problematic to transfer from the specialist clinic to primary care. In primary care it might be either a podiatrist, a nurse, or a doctor who evaluates feet. All of these have different professional roles and routines, and some might question whether D-Foot would improve their daily work, or just add to their workload.

In MoodMapper, the user has some of their behavioural patterns (such as step count and estimated sleep) automatically monitored, which means that there needs to be a great level of trust in data security. Likewise, it is important that an automated collection of data does not replace visits at the outpatient clinic, and that the staff still find value in face-to-face meetings.

#### Reflections from the workshop

The risk of complexity being neglected or ignored in this domain was discussed in the seminar. Participants agreed that, if an innovation is to become sustainable, it is crucial to map and involve all intended users. Accepting new work routines is less problematic if it has benefits for both patients and

staff, but if it results in a heavier workload without any tangible benefits, then the innovation might not gain popularity.

#### Complexity Domain 5: The Organisation(s) Implementing the Technology

*The complexity related to organisational issue is analysed in domain 5.*

##### The four cases

This domain was often intertwined with some of the other domains. All four cases found complexity related to the organisation, either anticipated or already experienced. In particular, there was no given pathway of idea-development-testing-verifying-implementation-spreading-sustaining for innovations through the system. It seemed to depend on finding the right key person, at the right level, for the right type of consultation, at the right time.

Again, most of the complexity in the post-project phase was related to ownership of intellectual property, management, and procurement. Different levels of the organisation had different types of complexity; so, even if the innovation itself and innovations in general were desired and welcomed, built-in regulations stopped its dissemination to other parts, risking the death of the innovation before it takes off.

##### Reflections from the workshop

The participants at the seminar expressed frustration over legal issues, as they had seen many innovators face legal and organisational complexity too late in the process. Focusing on the wrong thing at the wrong time could accumulate problems in the later stages of the innovation process.

#### Complexity Domain 6: The External Context for Innovation

*Complexities related to local and national context for the innovation are identified in domain 6.*

##### The four cases

Even though there is a national vision to be best in the world in eHealth by 2025 (32), the Swedish system of 21 independent regions makes it unclear/complex who is to decide about the local/regional/national development and implementation of innovations. Several different regulations need to be considered by innovators. For instance, there is a national initiative from the government to improve cancer care, but the regions are self-governed regarding budget and implementation. This means that, even if the regional cancer centre had a national assignment to improve cancer care generally, and the radiotherapy process in the local region specifically, it had no mandate to implement Digi-Do without the approval of the radiotherapy department at *each* separate regional hospital.

Further, if an innovation needs to be integrated with the IT-systems, as for the other three cases, national initiatives are ruled out by regional procurement, management supply-chains, and European regulations regarding medical devices (31).

## Reflections from the workshop

The tension between rules, regulations and innovations; between national, regional, and local context; and between bottom-up and top-down innovation processes, was also prominent at the seminar. It was suggested that this domain should really be assessed *first* of all, as a successful innovation process depends on the interplay between laws, regulations, initiatives, and guidelines from the different actors in the wider context.

### Complexity Domain 7: Emergence Over Time

*In domain 7, the sum of complexities from domain 1–6 is registered and viewed within a time frame of 3–5 years.*

Complexities were identified in all four cases (Additional file 3). When summarizing the complexities from domain 1–6, all authors concluded that the complexities are likely to increase in the coming 3–5 years, likely due to both advances in technology, and new regulations and standards.

## Discussion

In this study, we have retrospectively examined four cases of bottom-up innovations, using the NASSS-CAT long tool (20). All four cases came from the same Swedish region, thereby abiding to the same organisational support functions for innovation and IT. Similar to other studies (10), our results show that all four cases have suffered from various complexities during their development, making the work frustrating and implementation difficult to achieve.

By adapting the NASSS framework retrospectively, and specifically by using the long version of the NASSS-CAT, several complexities have been identified and many insights gained. During the process, several steps (Fig. 1) were taken to identify complexities in the seven domains. The insights from each of the domains are exemplified and discussed below.

## Domain 1. Insights about the illness

Some of the analysed conditions or illnesses became gradually less complex, as relationships between cause, function, and treatment were revealed. Other conditions remained complex due to comorbidity, lack of social support, lifestyle problems, or limited illness insight. Understanding possible complexity related to a specific illness and diagnosis can facilitate appropriate development of innovations.

In our study, the cases that addressed mental illness, and also diabetes, had more complexity related to the actual illness than the case aiming at preparing women before radiotherapy for breast cancer. It is notable that the *severity* of an illness is thereby not necessarily coherent to the complexity of it. The treatment itself may be complicated but well-known and researched, as in the case of breast cancer, with clear guidelines and care programs to follow and evaluate (33, 34). In contrast, a person affected by mental illness may have a relatively simple medical treatment (prescribed pills), but all other aspects, as

mentioned above, make the illness very complex. For diabetes, the timing of medication (insulin) in relation to food intake and exercise becomes complex (22). Although recommended, the annual foot checks for patients diagnosed with diabetes are not provided for all (24).

It can be a challenge to support healthcare staff in understanding what complexity entails and what aspects of the illness that are complex from the innovation perspective. Nevertheless, it became obvious during the analysis that this domain, at first felt deceptively easy to describe, made a great impact on the understanding of complexity. An initiated understanding of the complexity relating to the illness addressed in the innovation is thereby of great importance as a starting point.

## **Domain 2. Insights about the technology**

The level of technological complexity varies depending on the phase of the project: planning, development, or testing/evaluating. General awareness of the different technological requirements can prevent problems in the next innovative phase. Complexity can, however, increase when hindrances and obstacles for moving to the next step of development are discovered. Likewise, complexity can decrease when the needs for providing and managing the technology are clarified. Overall, piloting with stakeholders is key to clarifying practicability (35). If a new technological innovation is too demanding, or too unfamiliar to use, it is unlikely to become accepted by the intended users. Further, regulations about MDR (medical device regulation) (31) can cause unexpected complexity during the development phase, if not taken in consideration. As for the first domain, what initially seemed simple can in fact be complex, and vice versa, often due to intersectional transfers of digital data and software between different systems.

## **Domain 3. Insights about the value propositions**

Clinical testing of an innovation can, to some extent, prove its value or usefulness for end users, but is hard to evaluate if the outcome variables consist of soft values (for example reduced distress, heightened health literacy, and self-efficacy). Likewise, value and costs can be distributed across the organisation(s) in ways that are hard to assess. Will there be an initial or recurrent cost for the product, or will the cost be related to a new service that entails new tasks for staff? There is an advantage in specifying both costs and values, or the monetary costs as well as the effect of the innovation on other resources. Health economic analyses are thereby needed, but these are difficult to design and perform, as some innovations are focused on increasing soft values that are difficult to translate into monetary variables. A value proposition needs to be clearly described early in the process, to enable understanding of costs and outcome. Knowing how the innovation should be evaluated and the presumed increased value needs to be evident from the beginning of the project.

## **Domain 4. Insights about the intended adopters**

Roles, ways to work, and experiences are central for defining complexity relating to adopters.

It is beneficial to map and involve all users (direct or indirect) early in the development process, particularly as someone's gain might be someone else's pain. Co-production can enhance the three Rs in

research – Reach, Rigor and Relevance (36) – by ensuring that the correct needs are addressed and that the innovation is working practically for both patients and staff. There is a strong movement for involving patients in healthcare improvement, but if innovation is to be truly bottom-up, there needs to be a move from tokenism to sincere involvement (37), not least because patient involvement can provide more radical solutions or suggestions if used properly (38).

## **Domain 5. Insights about the organizational implementation**

Initial funding and development of bottom-up innovations from the local stakeholder within the organization is important to initiate the innovation process. Dissemination, at later stages, can be hindered by regulations. The IPF has the delicate task of supporting an innovator's creativity, but also of pointing out implementation-related complexities early in the process. Likewise, finding out too late that the project will fail due to complexity is detrimental. Supporting bottom-up innovations thereby requires in-depth knowledge of the complexity of healthcare systems.

In this study, the involvement of the IPF was seen as an advantage, as much of the frustration from the innovators could be located and discussed with IPF through NASSS and the use of NASSS-CAT as a shared language. Having dialogues and workshops together created a learning process for all involved, something that has been found beneficial in new projects (13). Even if the identified complexity persists within the organisation, bringing it (and the challenges it involves) to the surface and acknowledging it is of uttermost importance. But above all, the right competence needs to be accessible to provide support for innovators. Resources such as experts in immaterial properties, medical device regulations (31) and GDPR (39) for all levels of the innovation process, is something not yet completely in place in the Swedish region studied (40).

## **Domain 6. Insights about the external context**

Innovations outside existing systems risk becoming a “lonely island” and, therefore, infrastructure for system integration is needed. Innovations supported by different actors with different perspectives have a better chance of survival (35, 41). Being able to define a clear benefit of the innovation early in the process is beneficial for dissemination. Integrating research with innovation projects can create synergies that enable high-quality development and evaluation, thereby providing networks for dissemination and implementation in a wider context. The wider the intended spreading of the innovation (from local to regional and/or national), the more complex it becomes. Again, highly qualified competence is needed right from the start of a project, and existing structures for innovation needs to be challenged. If regional support is only allowing regional use, there will be no dissemination and bottom-up innovations thus risk becoming only local, or, at worst, die the “death of innovations” after the initial project phase.

In bottom-up innovation, complexity has been argued to play a significant role for many projects that do not succeed or move on from a project to implementation (1). The chosen methods, e.g., the NASSS-CAT, in its English version, have been useful in this study to identify complexities. Awareness of pitfalls/complexities in one's own or others' projects gives the bottom-up innovator a chance to see whether similar complexities exist in other innovations.

Healthcare is indeed a complex system per se, with a history of “silozation and pillarization”, both in Sweden and in comparable countries (42, 43), as challenges requiring interorganisational collaboration are well recognized (35, 41). For actors within such systems to both excel in their retrospective area of expertise and simultaneously work with innovation and improvement, there needs to exist mechanisms and models to both explain why things work (or don't work) as well as to help the individual to move forward (41). There have been several takes on how to spread and scale-up improvements, such as those presented by Greenhalgh et al. (7).

### NASSS-CAT and CCA Method

The authors experienced that, before using the NASSS-CAT long tool, users need to first be familiar with the NASSS framework (10). We suggest that, besides reading the literature describing the NASSS framework, experienced NASSS-CAT users should support new NASSS-CAT users. The current study was strengthened by the support one of the authors who was involved in the development of the NASSS-CAT tools (20). As a complement to the NASSS-CAT long tool, other templates are available (20). The NASSS-CAT long tool seemed deceptively easy at first, but was more difficult to use than expected, and the need for a CCA became apparent during the work. During the CCA analysis of the four cases, the innovators had discussions about how to interpret the questions in the seven domains of the long version. The four innovators contributed with multiple perspectives based on their own cases and discussed their different understandings of the narratives, the domain questions, and the sub-questions. The use of CCA statements and negotiations on how to interpret the questions in the NASSS-CAT thereby facilitated the NASSS-CAT analysis.

The authors experienced that the process of comparing first how each innovator interpreted the questions probed, and how this then was adapted to each case, was a challenging and time-consuming task, indicating that the NASSS-CAT long tool requires profound knowledge of both the theory of complexity as well as the context around the specific innovation. Further, even if the tool helps in identifying where complexity exists, it does not solve the issue.

This study acknowledges the prominent complexity in the innovation process of four separate cases in the same regional settings, as well as the workability of the NASSS-CAT LONG tool. The NASSS-CAT project tool could be a more relevant alternative to use at the early stages of an innovations process in order to consider the potential complexity of future steps, thus easing the path for the innovation to move towards possible implementation.

### Strength

The NASSS-CAT framework was developed from thorough review of literature and clinical cases (10, 20), but, to our knowledge, the tools have not yet been substantially tested for their ability to unveil complexity in bottom-up projects. Therefore, this study contributes both to increased knowledge about complexity in bottom-up innovations and to evaluation of the NASSS-CAT long tool. The study's strength lies in the four

different cases representing both somatic and psychiatric care, and the innovators' long experience of both health care and eHealth.

### Limitation

The retrospective NASSS-CAT analysis of the four cases was mainly performed by the four innovators, respectively, without direct input from stakeholders. This meant that only one perspective from the many actors involved in each project was put forward. The rationale for this was that each innovator had already faced, and were therefore acquainted with, the diverse complexities addressed in all seven domains. However, other perspective might have improved the analysis further.

## Conclusions

This study increases knowledge of the prominence of complexity in bottom-up innovations within public healthcare and contributes to the understanding of the workability of the NASSS-CAT long tool. Using a validated tool early in the process of innovation is helpful but requires profound knowledge about complexity and the system in which the innovation is supposed to be implemented. Even if bottom-up innovations are developed within the same support organization, complexity varies depending on the phase of development process. Finding and defining complexity does not solve the issues but will increase the possibilities for implementing the innovation if the right competence is available to support this.

## Abbreviations

CCA: constant comparative analysis

CAT: Complexity Assessment Tool

DFU: diabetic foot ulcers

IPF: Innovation Platform

NASSS: Nonadaptation, Abandonment, and challenges to Scale-up, Spread, and Sustainability

RT: Radiation Therapy

VGR: Region Västra Götaland

## Declarations

Ethics approval and consent to participate

Not applicable.

## Consent for publication

Not applicable.

## Availability of data and materials

The datasets generated during and analysed during the current study are not publicly available because the innovations are under development and need to be protected from plagiarism. Data are available from the corresponding author on reasonable request.

## Competing interests

The authors declare that they have no competing interests.

## Funding

Not applicable

## Authors' contributions

UT designed the study, performed the analyses, interpreted the results and contributed to writing the manuscript. FS designed the study, performed the analyses, interpreted the results and contributed to writing the manuscript. ULK designed the study, performed the analyses, interpreted the results and contributed to writing the manuscript. AG designed the study, performed the analyses, interpreted the results and contributed to writing the manuscript. All authors read and approved the final manuscript.

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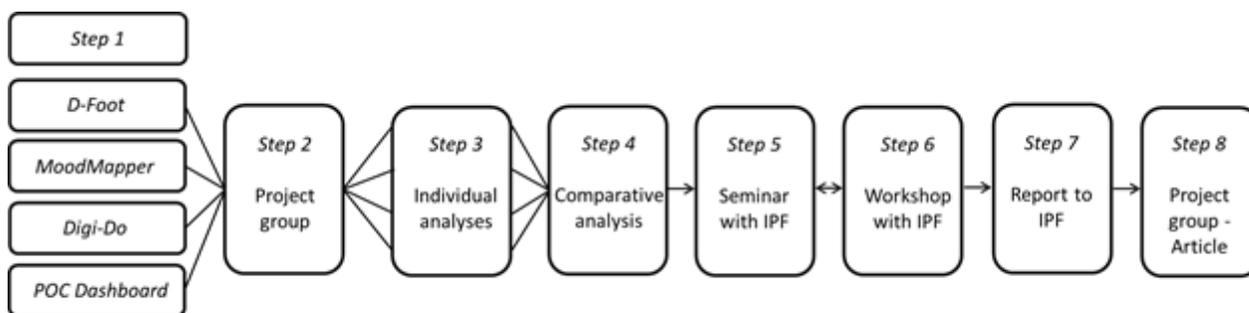
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## Figures



**Figure 1**

A flowchart illustrating the study's process for analysing complexity in bottom-up innovations

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