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Implementing and Embedding Health Informatics Systems – Understanding Organizational Behaviour Change Using Normalization Process Theory (NPT)

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Abstract. Successful implementation of health informatics systems depends not only on efficient performance of intended tasks, but also integration into existing working relationships and environments. Implementation is an understudied area in health informatics research, and relevant empirical evidence is often absent from strategic decision making. Implementation theories such as Normalization Process Theory (NPT) can help address this gap by providing explanations for relevant phenomena, proposing important research questions, and framing collection and analysis of data. NPT identifies, characterizes, and explains mechanisms that have been empirically demonstrated to affect implementation processes and outcomes. These explanations are generalizable and facilitate comparative investigations. The first section of this chapter introduces the four main constructs of NPT (coherence, cognitive participation, collective action, and reflexive monitoring) and their constituent components. Each component is discussed with reference to a real-world example, and relationships between the four constructs are explored. The second section explores how NPT has been applied in both prospective planning of interventions and their evaluation, as well as retrospective exploration of factors promoting or inhibiting successful implementation. We examine two examples from published literature: firstly, prospective planning of an evaluation study on implementation of a digital health intervention for Type-2 diabetes; and secondly an evaluation of implementation of a new electronic preoperative information system within a surgical pre-assessment clinic. The chapter concludes with reflections on some limitations of NPT as a theoretical framework.

Keywords. Implementation science, Process evaluation, Organizational behavior change, Change management, Developer-user co-design

Learning objectives

After reading this chapter, the reader will be able to:

1. Understand the basic NPT framework, and describe the four main constructs;
2. Be familiar with example applications of NPT relevant to health informatics;
3. Understand how to apply NPT in prospective planning and evaluation of implementation of health informatics systems.

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1. Introduction to Normalization Process Theory (NPT)

'Implementation theories are useful. They provide explanations for relevant phenomena, propose important research questions, and frame the collection and analysis of data. These explanations are generalizable, and facilitate comparative studies. Implementation researchers now have a wide range of useful theoretical tools at their disposal…Normalization Process Theory (NPT), is one of these. It identifies, characterizes and explains mechanisms that have been empirically demonstrated to motivate and shape implementation processes and affect their outcomes.' [1]

Why are new technologies and working practices implemented successfully in some settings, but not in others? What affects whether a new technology or practice will be implemented in the first place, and whether it will 'stick' in the longer term (that is, become incorporated into routine work within an organization)? NPT has developed from empirical attempts to answer such questions[2]. In this first section, we will explore the theory in terms of its main constructs and their components, to understand how NPT provides a framework for understanding implementation[3].

1.1 Understanding implementation as a set of processes

NPT focuses on *action* (both individual and social) - that is, what people *do*, rather than what they say or think – and on the *processes* through which these actions take shape. NPT is grounded in the premise that implementation of an e-health or informatics application involves human actors in four things: (i) changes in goal-directed interactions with material and virtual things (physical infrastructure, hardware and software); (ii) relational restructuring (changes in the experience and organization of human relations); (iii) normative restructuring (changes in the rules and resources that make action possible); and (iv) organizing logics (changes in the ways that whole systems are defined and understood). From these stem *specific kinds of work* and it is from these that implementation processes are derived [2]. These are: *Coherence, Cognitive Participation, Collective Action,* and *Reflexive Monitoring*. Each construct has four sub-components, which set out more specific kinds of work that occur within each domain. The remainder of this section will describe these elements and their relationship within the overall framework (readers may also view the Appendix which illustrates the relationship between constructs and their components as tables).

1.2 Making sense of new technologies and practices (Coherence).

Coherence relates to 'the *sense-making work* that people do individually and collectively when they are faced with the problem of operationalizing some set of practices' [3]. Sense making is the work that people do to understand that the intervention and its associated practices.

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[2] Readers wishing to further explore the history and context of NPT development may refer to the 'Background' section of May et al.'s (2018) systematic review of NPT use in feasibility studies and process evaluations [1],

[3] This chapter will not discuss relations between NPT and other theories of implementation or organizational and/or behavioural change, as it is beyond the scope of the article. Readers interested in further comparative exploration of NPT in relation to other such theories may refer Moullin et al.'s (2015) systematic review of implementation frameworks relating to innovations in healthcare [16].

1.2.1 *How is what is being implemented different from what already happens? (Differentiation)*

Differentiation refers to the work that people do to understand how a new ensemble of practices is different from what came before. For example: a group of clinicians implementing a video conferencing system to interact with patients will likely want to understand how this new practice and its objects (i.e. video consultation equipment) operate differently from in-person consultation (both in terms of clinician patient interaction, and how new objects interact with other existing tools, protocols, and diagnostic implements) [3].

1.2.2 *What does the intervention mean for team working? (Communal Specification)*

Healthcare is commonly delivered by teams, many of which involve clinicians and other professionals with different skill sets and contributions to overall patient pathways. This activity involves team working, including both immediate collaboration within the same physical setting, and remote working between individuals and teams based at different locations. Introducing new technologies and ways of working therefore has the potential to change working relationships. Making sense of interventions therefore also involves questions such as, 'what needs to be done, by who, and when?' [3]. For example, the rationale for changes to information recording systems may be to reduce workloads and/or improve accuracy and responsiveness. However, this also implies changes to the tasks and divisions of labour associated with record keeping. If we imagine the hypothetical case of a new electronic health record (EHR) being implemented into a General Practice (GP) clinic, questions around *Communal Specification* might include: how will the new system change who records and/or retrieves patient information? Are these changes the same for all information pathways within the service (e.g. does it affect the pathway of care for patients managing asthma in the same way as for patients managing a mental health condition)?

1.2.3 *What does the intervention mean for specific people? (Individual Specification)*

Making sense of interventions also has an individual component; that is, how interventions will affect the tasks and responsibilities of specific people. For example, staff recruiting patients to a clinical trial need a strong understanding of the work required to secure informed consent from patients (i.e. how the conditions of a new trial will affect their specific tasks and responsibilities in recruitment) [3].

1.2.4 *How do participants see the value of the intervention? (Internalization)*

While understanding the practical aspects of the intervention (i.e. what is new, what it means for team working as well as individual responsibilities) is vital, it is also important that participants see the *value* of what is being implemented. Returning to the example of a video conferencing system for remote consultations, we might ask *how* clinicians involved in its implementation come to see its worth (or not) [3].

1.3 Establishing relationships and divisions of labour to support the intervention (Cognitive participation).

Cognitive participation refers to 'the relational work that people do to build and sustain a community of practice around a new technology or complex intervention'[2]. While making sense of an intervention is a necessary step, successful implementation also requires that participants use this knowledge to establish responsibilities and divisions of labour that will support it. The components of *cognitive participation* point to the more specific sub-types of work that take place within this domain

1.3.1 *Who are the key people and what are they doing? (Initiation)*

Implementation of new technologies or practices in healthcare services is often delegated to a small group of managers and professionals [3]. These people frequently take the lead in setting up systems, procedures, and protocols, as well as engaging with others involved in implementation to ensure that necessary actions are undertaken. This construct draws our attention to questions of process: how have key people been identified? How has their role been established?

In the case of the EHR implementation within a GP surgery, we expect that (at least) four kinds of key people will exist: clinicians (who retrieve information for the purpose of providing treatment and care); administrators (who provide support to clinicians through information work); specialist health informatics and IT staff (who support implementation with specialist knowledge and skills); and patients (who are directly and indirectly interacting with this system as those move along pathways of care and treatment). Our focus here is on *how* key people are identified as such, and what events take place to *initiate* their involvement in this regard. The relative visibility of key people within different role groups may depend on their relationship to those driving implementation. For example, if implementation of the EHR is driven primarily by clinicians and IT staff, the significance of administrators may not be immediately obvious to these project leads if their regular working practices do not expose them fully to the relevant functions of this group. Successful identification of key people and their *initiation* as such therefore requires detailed investigation of both formal and informal contributions within complex healthcare processes. Informal conversations with staff at all stages and levels of involvement can be just as valuable as more formal types of data (e.g. role descriptions) in informing both planning and evaluation of implementation with respect to *initiation*.

1.3.2 *How do participants become involved in the intervention? (Enrolment)*

Identifying participants and involving them in the work of implementation extends beyond key people; we also need to explore the practical processes by which others will be involved in implementing the intervention. Returning to the previous example (i.e. a new EHR within a GP clinic) we need to think about how different people will be bought in (or *enrolled*) as active participants. This is not the same as gaining consent to implement or change something but refers to the processes by which people become *actively* involved. Enrolment thus depends to a large degree on understanding the context in which participants operate, and again the focus is on *how* this occurs. For example, some initiatives may invite staff to take on specific tasks to drive implementation, and make them explicit points of contact for other staff affected by the intervention.

Implementation of the EHR might involve staff within different GP surgeries, or different role groups within the same surgery (e.g. reception, community nursing), actively seeking feedback on proposed changes and/or eliciting questions about implementation from colleagues.

1.3.3 *Why should a person participate? (Legitimation)*

Successful involvement of key people in the intervention, as well as wider enrolment of those working in the implementation space also implies that those involved believe that it is right for them to be, and that they can make valid contributions [3]. Organizational behavior change projects in health (such as improving infection control, or nutritional care for older people) often involve attempts to widen the sphere of concern with a particular activity (e.g. information governance, child protection, infection control) by, for example, stating that a given area is 'everyone's responsibility' [4–6]. Often, perceptions of legitimacy may be constrained by membership of specific professional groups (e.g. a nutritional care intervention might be seen initially as the exclusive responsibility of dietitians). Additional relational work is therefore often necessary to establish legitimacy with other groups. In the case of health informatics interventions, this may involve establishing relationships by meeting directly with clinicians and administrators using the system and establishing an understanding of *how* they will contribute to intervention and development.

1.3.4 *What processes will support people staying on task? (Activation)*

Projects in which participants have made sense of an intervention (*coherence*), identified key people (*initiation*), and bought those involved on board (*enrolment*) are well placed to begin initial implementation of their intervention. In these initial stages the tasks, relationships, and resources that have been established to support this work are *activated* – that is, they 'go live' and enter everyday work. These processes, being new, are vulnerable to various forms of disruption, particularly in settings where they compete with other tasks for the time and attention of participants. Processes associated with *activation* are the practical means by which those involved will be stay 'on the case', and how potential points of disruption may be identified and dealt with [3].

1.4 The operational work of implementation (Collective action)

Having made sense of the new set of practices and objects associated with the intervention (*Coherence*) and undertaken the relational work of understanding who should do what in the initial implementation of new practices (*Cognitive Participation*), we turn to the actual processes of implementation. Components in this construct highlight forms of operational work commonly necessary to support initial implementation.

1.4.1 *How does the intervention affect existing working practices and relationships? (Interactional Workability)*

Once the intervention goes live, is it in any way disruptive to normal ways of working? Does it 'get in the way' of other activities? While other constructs have pointed

to sense making and organizational work in which key people may seek to anticipate these outcomes, it is often the case that complex interventions will require additional adaptive work as implementation progresses.

For example, a key problem of telemedicine systems historically has involved additional work required in communication and interpretation of complex clinical information, when compared with co-present consultations [7]. What we are interested in with respect to *interactional workability*, is the work that people have to do with objects (i.e. the physical implements that accompany an intervention, such as a new interface for patient record retrieval), new practices (e.g. a new way of performing diagnostic assessments), and each other to accommodate and adapt to new ways of working.

1.4.2 *How are confidence in, and accountability for the intervention built? (Relational Integration)*

Relational integration refers to forms of *knowledge work* that participants do to build accountability and maintain confidence in a set of practices and the people involved with them. Accountability can here be thought of as processes that give participants access to information (e.g. formal reports, or informal observations) about the outcomes of a given practice. Through such processes, confidence in an intervention and its associated practices and objects can be built and/or undermined. For example, confidence in a new teledermatology intervention was undermined when clinicians began to doubt the integrity of the images transmitted by the system, and began to examine patients in person alongside digitized images (resulting in greatly increased workload and increased pressure on their clinical department) [7]. Clinicians in this case undertook knowledge work that resulted in a loss of confidence in what was being transmitted, indicating not only *why* confidence was undermined, but *how*, and thereby identifying a point of failure at which such issues might be addressed (e.g. through development of image verification procedures that help clinicians to build accountability and confidence in the system).

1.4.3 *Who does what? (Skill set workability)*

Who should perform a given task? What are the processes for allocating responsibilities as the intervention progresses? Are they formal (for example, allocation by rota, or contractual changes to responsibilities), or informal through voluntary agreements between participants. Implementation of complex interventions often requires adaptation and renegotiation of roles and responsibilities, which can involve trade-offs between resource allocation (i.e. the time that specific people can contribute) and degree of need for specialist knowledge within a given part of the process. For example, a research group investigating the effectiveness of a decision aid for medication choice after a serious illness event had to decide whether the decision aid should be administered by trial managers with no clinical responsibility for the patient, or nurse practitioners actively involved in their care [3,8]. The trade-off here was between those with greater familiarity with and attachment to the intervention, compared with those closer to the field in which the decision aid intervened (i.e. the care pathway of patients recovering from serious illness events).

1.4.4 *Who gets what, and how? (Contextual integration)*

Successful interventions depend not only on individual and collective divisions of labour, but on allocation of resources to support them. *Contextual integration* looks at how practices and objects become (or fail to become) integrated within the wider context of the intervention setting, in terms of available resources. This component focuses on the processes through which resources are allocated as the intervention project progresses, involving questions such as: who has authority to allocate resources, and to what degree? Are those implementing the intervention able to access additional resources to deal with emergent challenges?

Returning to our earlier example of a GP surgery implementing a new EHR, we might explore whether administrators are able to access specialist knowledge support during implementation to help them work with the new system.

1.5 Evaluating implementation to promote embedding (Reflexive monitoring).

Having conducted the work of initial implementation, we need to consider how participants appraise the success of the implementation project as a whole, as well as the specific practices and objects associated with it. Components of this construct focus on kind of work done to evaluate the success of the intervention, analyse its impact on working relationships and individual practices, and (if necessary) make changes to it.

1.5.1 *How is information obtained to support appraisal work (Systemization).*

What informs how people appraise success, and how is this information obtained? Does information flow in the same way to all participants, or do some individuals and groups gather knowledge that others don't? Systemization may involve formal processes, such as the gathering of outcomes data within a randomized controlled trial. However, participants may also make use of information gathered through informal processes in both individual and collective appraisal (e.g. anecdotal examples of problems in practice) [3].

1.5.2 *How do participants work together to appraise the intervention? (Communal appraisal).*

Participants often work together to evaluate the worth of interventions (overall or in part), and these can involve formal processes such as team meetings, or informal groups (e.g. coffee break conversations). Different kinds of meeting may involve different processes that affect *how* the appraisal process is conducted. Formal meetings may have agendas structured around discussions of specific kinds of information (e.g. outcomes data from an RCT). They may also involve implicit or explicit divisions of labour that affect the kinds of information that enter discussions (e.g. formal meetings of consultants may exclude the informal observations of other participants). Likewise, unstructured appraisal may favour specific kinds of information (e.g. informal observations from practice) over others. The significance of this component is to recognize the kinds of appraisal work that are occurring within the field of implementation, and how these may affect the ways that participants understand and work with aspects of the intervention.

1.5.3 *How do participants evaluate the impact of the intervention individually? (Individual appraisal)*

Communal appraisal processes are also related to the work that individuals do to evaluate the impact of interventions of their own work, as well as the contexts in which they are set. Thinking back to our earlier example of the EHR within the GP surgery, individual clinicians may evaluate not only the worth of the programme, but its impact on their other tasks. If the system complicates and increases their workload, this may lower the value of the intervention to the clinician regardless of the overall impact on other areas of work within the surgery. From the point of view of understanding implementation, the focus here is on the processes by which individuals appraise the intervention, and the context in which different participants operate may influence this (i.e. the context and priorities of clinicians and administrators may differ relative to the other activities in which they are involved).

1.5.4 *Can participants modify aspects of the intervention, and if so how? (Reconfiguration)*

Appraisal work, both individual and collective, may lead to attempts by participants to modify practices associated with the intervention, or even aspects of the objects associated with it (e.g. diagnostic tools, patient information systems). For example, those leading implementation of the (hypothetical) EHR within a GP surgery may evaluate whether the benefits of the new system outweigh additional costs in terms of extra time or resource investment in using it. If they feel that aspects of the system negatively impinge on other important kinds of work, they may seek to modify aspects of the system. Depending on intervention design and the setup of implementation, this might involve asking developers to redesign some part of the front end, or to add features that allow it to integrate with other information systems within this space. However, more informal attempts may also be made to reconfigure how they work with the system ("work-arounds"), particularly if a route to requesting formal changes is not visible or practical. This may result in aspects of the new system being used alongside other systems or practices, in ways that were not anticipated by developers, and were not part of the original intervention design.

1.6 Relationships between the constructs

The ordering of constructs follows a general pattern from initial sense making, through organisational work to prepare for implementation, then the operational work of implementation, evaluation of its success, and potential reconfiguration. However, other kinds of connection between constructs are also possible, particularly following initial implementation when embedding the new procedure over a longer period may require revisiting or revising earlier steps. For example – work to set up the intervention, which would fall under the domain of cognitive participation, may reveal unforeseen implications for service, that require revisiting some earlier sense-making processes to address them and move forward. Similarly, evaluation work following initial implementation of an intervention that would map the *reflexive monitoring* construct, may reveal issues relating to how different people made sense of the intervention, that were not apparent until it went into service, and requiring changes to *coherence*-related activities. *Coherence*-related activities may also affect reflexive monitoring processes –

for example, if during *collective action* some feedback from a staff member indicates a significant area that the intervention is likely to affect, that was unlikely to be picked up by processes relating to reflexive monitoring, this could lead to changes in the programme design. Finally, we may simply see gradual changes made to the work of implementing interventions, which would come under collective action, because of findings related to reflexive monitoring. What these indicate is that implementation processes identified by the constructs may not proceed in a strictly linear fashion but encounter difficulties and go through revisions as they evolve.

1.7 From implementation to normalization – embedding new practices as routine aspects of care.

We began this section by noting that NPT focused on action, and we will conclude with an example indicating the importance of this for implementation in general. Figure 1 shows results from an investigation (a theory-led review) of systematic reviews into professional behaviour change in healthcare [9]. Along the top of this matrix we can see the NPT constructs and components, while the left-hand vertical distribution shows different types of professional intervention as defined by the Cochrane EPOC (Effective Practice and Organisation of Care) system. Studies in the review have been grouped by type, and each group has been ranked in terms of their success at effecting and sustaining professional behaviour change. The red boxes indicate which components of NPT were covered by the intervention, and these show a positive association between success of interventions, and their emphasis on the *collective action* and *reflexive monitoring* aspects of the intervention. On the basis of this, the review authors hypothesise that interventions which focus on attitudinal change are less likely to be effective in achieving long term behaviour change than those that reinforce new practice norms and associate them with peer and reference group behaviours [9]. Changing attitudes and building value are necessary activities, but may not suffice to ensure long-term success.

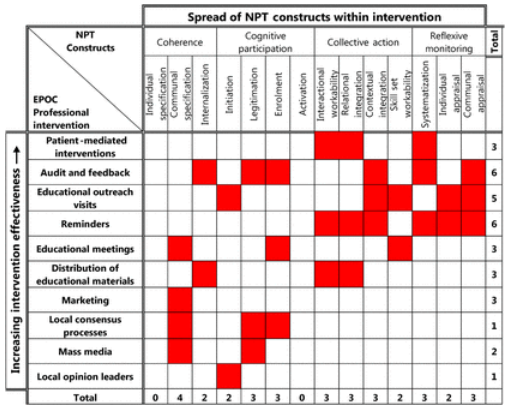

Figure 1 - Positive relationship between intervention effectiveness and focus on Collective action and Reflexive monitoring aspects of NPT [9].

2. Use of NPT in health informatics and service development

Having given an overview of NPT, we will now explore how the theory has been applied in both prospective planning, as well as ongoing and retrospective evaluation of implementations in health informatics contexts. We will examine two examples from published literature: firstly, an example of prospective planning of a digital healthcare intervention for management of diabetes [10,11]; and secondly an evaluation of implementation of a new electronic preoperative information system within a surgical pre-assessment clinic [12]. These two cases will serve as examples of how NPT has been used to plan and evaluate successful implementation of new health informatics systems, and identify mechanisms involved in this process.

2.1. Prospective planning of an evaluation study on implementation of a digital health intervention for Type-2 diabetes

Effective self-management is essential to good health outcomes and the prevention of associated complications for people with type 2 diabetes [10]. The UK National Institute for Heath and Clinical Excellence (NICE) recommends structured education to teach self-management; however, evidence suggests that only a small proportion of patients are offered this service, with fewer eventually attending [10]. Ross et al. developed an internet based self-management intervention: "HeLP-Diabetes: Healthy Living for People with Type 2 Diabetes", allowing patients to access self-management measures recorded by their GP surgeries, as well as information resources based on NICE guidance designed to complement existing in-person group education programme [10]. In planning implementation of *HeLP-Diabetes*, Ross et al. needed to consider how they would: determine uptake and use of the intervention by services and patients; identify factors promoting or restricting use; identify resources needed for successful implementation; and explore possible intervention effects on self-reported patient outcome measures [10]. The authors used NPT as an explanatory framework to explore the implementation process and guide interviews with NHS staff, using constructs and components as sensitizing resources (i.e. as indicators of general processes and kinds of work relevant to the outcomes of interest) [10]. Data collection also included informal feedback from staff at GP practices, collected by one researcher leading the implementation, as well as usage data from the *HeLP-Diabetes* software on number of patients signing up and the GP practices at which they were registered [11].

Ross et al. used NPT in analysis of interview, feedback, and usage data to develop an implementation plan for *HeLP-Diabetes*, in which specific implementation strategies were developed to target challenges mapped to the main constructs of NPT (see table 1). *Coherence*-related strategies included identifying key people within the local Clinical Commissioning Group (CCG – the body responsible for commissioning of services locally) as well as GP practice managers and leads [11]. This strategy allowed for targeted provision of educational materials emphasizing *HeLP-Diabetes* as an online system distinct from other self-management programmes, and its status as a free-to-use resource developed by a university. These strategies helped support *Differentiation* between *HeLP-Diabetes* and existing resources, and *Internalization* of value by drawing attention to its lack of cost to users, and the legitimacy of the developing body [11]. The implementation team also held educational outreach visits with healthcare professionals (HCPs) in which the nature of the programme, its evidence base, theoretical basis,

participatory development, and benefits for patients as healthcare processes and organizations were discussed [11]. These conversations completed educational material by allowing potential adopters to explore questions regarding implications of the system for their own practice, as well as its efficacy, in deciding whether or not to adopt *HeLP-Diabetes* [11].

Table 1. Implementation strategies for *HeLP-Diabetes* targeting NPT constructs (adapted from [14]).

Coherence	Cognitive Participation	Collective Action	Reflexive Monitoring
Local opinion leaders	Interprofessional education	Educational meetings	Continuous quality improvement
Educational materials	Local consensus processes	Tailored interventions	Audit and feedback
Educational outreach visits	Educational materials		Reminders

Strategies to support *Cognitive Participation* included provision of a training session for HCPs to understand the actions and procedures necessary to ensure sustainable and successful implementation of the intervention [11]. Training sessions also included opportunities for staff within specific implementation sites to explore implementation with respect to local working contexts [11]. This was an important step in ensuring that implementation was flexible enough to accommodate planning for local contingencies (e.g. differences in how work is assigned within teams, methods of communication with patients).

Educational meetings and materials were also used to provide ongoing support for *Collective Action* processes during implementation. HCPs were given access to the *HeLP-Diabetes* system, allowing them to explore: how the intervention fitted the skill sets of staff; what resources might be necessary to support implementation at different sites; the knowledge necessary for HCPs to develop confidence in using the system; and how it might impact on interactions between colleagues, and with patients [11]. This process was supported by educational materials in the form of training booklets to support staff in becoming familiar with system functions (i.e. creation of a login, signing up a patient) [11].

Continual engagement with staff across the period of implementation also served a *Reflexive monitoring* function, as staff suggested that they would offer *HeLP-Diabetes* to patients more if they were receiving a greater number of related enquiries from patients [11]. This led to development of additional patient-focused advertising strategies to increase awareness including: TV screen adverts in waiting rooms; talks given at self-management groups; attendance at Diabetes UK events; coverage in practice newsletters; and mass mailouts to all patients at some implementation sites [11]. What is interesting to note here is the relationship between *Reflexive monitoring* in the form of staff feedback, and its use in revision of *Collective action* processes relating to *Interactional workability* (that is, a suggested change to the implementation strategy targeted at the relationship between HCP and patient) [11].

2.2. Evaluating implementation of a new electronic preoperative information system within a surgical pre-assessment clinic.

Surgical pre-assessment clinics (PACs) evaluate whether patients may be suitable for day case surgery or 23-hour care, or may require a longer in-patient stay. These have been introduced in Scotland as a result of policy recommendations intended to reduce unnecessary burden on services, and reduce surgical mortality rates [12]. PACs act as a gateway to surgical services from a wide range of referral pathways, involving multiple information flows. The PAC design evaluated by Bouamrane and Mair (2014) incorporated development and implementation of an electronic pre-operative information management system, to facilitate information sharing among members of the multidisciplinary PAC team. Development occurred iteratively by PAC staff in collaboration with the local NHS Health Board Information Technology team. In this article, the authors focus on one site (Dumfries and Galloway Royal Infirmary - DGRI) from a national study in Scotland. The authors modelled clinical processes using process-mapping techniques, and conducted 10 semi-structured interviews with five participants across four visits to the clinic site [12]. NPT was used in analysis of results from both process mapping and qualitative interview data.

The rationale for the clinic was found to be well established at DGRI, supported by previous institutional experience of problems with traditional in-patient routes lacking pre-assessment. In addition, the importance and relevance of the service was reinforced by national policy initiatives that incorporated performance targets. *Coherence* of the PAC in terms of overall relevance to strategic objectives of the institution was therefore well established. *Coherence* was also found to be high within the pre-assessment clinic, but less so at points of contact with other services. This was attributed in part to the number of different possible pathways to the PAC which were observed to be confusing to staff within the clinic, in addition to the fact that junior doctors involved in various routes to the PAC were not routinely involved in the clinic's assessment processes.

The collaborative design of PAC implementation and development, particularly with respect to the pre-operative information management system, was reported as a strength of the project. The authors report a 'teething period' of 12 months, after which specialist nurses leading PAC development were 'entirely satisfied' with information management practices. The combination of leadership from experienced pre-surgical nurses, and collaborative ongoing development with local NHS IT services ensured that key people relating to both clinical and health informatics aspects of the project were working together to drive forward development (an aspect of *Cognitive participation*).

Staff within the multi-disciplinary team (MDT) were found to be highly experienced in care and management of day-case patients. This foundation allowed PAC staff to effectively define their roles in relation to the new clinic, and build both individual and collective understandings of accountability (*collective action*). At the level of the wider institution however, participants expressed concerns with respect to replication by the PAC of information available through other sources (i.e. primary care). Here, the authors note that such concerns may in principle be addressed through improvements to integration of existing information systems. In the context of *Collective action*, such a development would require extending professional relationships through which roles are defined to encompass inter-departmental working (i.e. who is responsible for which tasks within an overall care pathway). Finally, although the prior experience of PAC staff was important in the success of the nurse-led clinic design process, there were no formal processes for continuing professional development or training at the PAC (*reflexive*

monitoring). Transfer of knowledge on PAC procedures and related practice updates was observed to occur informally during other work, leaving the intervention vulnerable to staff attrition (as no formal process existed to ensure that this knowledge was transferred to new appointees).

2.3. Limitations of NPT

Before concluding with an exercise to help readers apply NPT to health informatics developments we will discuss some of its limitations, the first of which concerns lack of sensitivity to wider contextual factors beyond the immediate site of implementation. For example, Clarke et al. (2013) used NPT to evaluate implementation of a training programme for carers of stroke patients, within a cluster randomized controlled trial (RCT) [13]. The multi-site nature of this trial meant that variations in implementation context were present at the local level (e.g. service, resources, divisions of labour), in addition to regional and national policy changes (with differences in local responses to such changes providing further sources of complexity). In their evaluation, Clarke et al. noted that while NPT had been useful for identifying mechanisms and processes that inhibited implementation of the training programme, it did not capture the impact of these wider contextual factors [13]. At a national level, recruitment to the cluster RCT began shortly after the launch of a new National Stroke Strategy in 2008 [13]. In addition, many sites experienced competing demands on MDT members', patients', and care givers' time and resources from other service development initiatives [13]. All the hospital services involved were working towards the goal of stroke survivors spending all or part of their stay on a stroke unit, while most were also planning or introducing thrombolysis services. In addition, many sites were introducing early supported discharge schemes or reorganization of existing services, which required changes in staff locations and roles. While the impact of these factors may have been visible indirectly through their impact on other kinds of process identified through NPT (e.g. *Resource allocation*), Clarke et al. found that theory did not account fully for their role in the implementation context.

These observations indicate both the vulnerability of service developments (including health informatics innovations) to organizational turbulence, and how building relationships and processes that are resistant to such turbulence is essential in complex healthcare settings. They also indicate the importance of attending to contextual factors that shape implementation processes, a concern that has driven ongoing development of the theory [14]. In addition, authors such as Johnson et al. (2017) have sought to address these limitations in their application of the theory, by presenting adapted models that link the constructs with wider organizing structures and social norms (e.g. policies, public expectations of services, political contexts – see Figure 2). Elsewhere, in a systematic review of NPT use in feasibility studies and process evaluations, May et al. (2018) noted a number of additional criticisms from researchers: that NPT constructs overlapped; that the technical vocabulary of the theory was difficult; and that as a result coding qualitative data was difficult [1]. May et al. noted that problems of this nature seemed less evident when researchers used a more inductive approach to qualitative data analysis than they did when authors employed a framework approach [1].

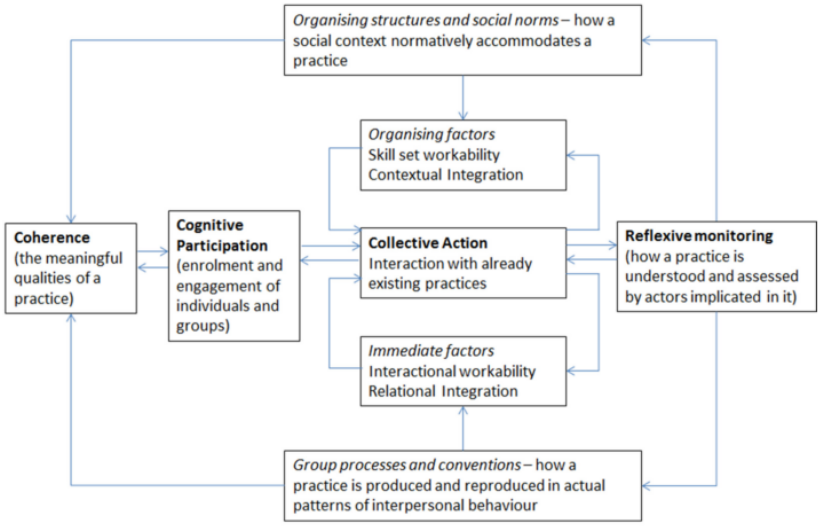

Figure 2. Johnson et al.'s (2017) adapted model of NPT [15].

3. Exercise

As we have seen, NPT can be used in prospective planning, as well as ongoing and/or retrospective evaluation of implementation of new technologies and processes. In this final section, we present a worked example of how NPT may be used to frame research questions for either purpose. It is important to note that this is only one way in which the theory has been used, and that other applications may be appropriate for different implementation projects. For an overview of how NPT has been applied in study design, data collection and analysis, we recommend that readers consult the 2018 systematic review conducted by May et al [1].

The exercise will involve using NPT to derive research questions in relation to implementation of a hypothetical health informatics system. To do this, we will use tables (see Appendices) containing descriptions of NPT constructs and components as a tool for linking research questions to components of the theory. We will provide a worked example for a single component, after which we invite readers to continue the exercise with remaining questions.

3.1. The scenario

Background - A community team of HCPs (comprizing nurses, occupational therapists, and dietitians) are implementing a new electronic patient record system for screening and treatment of malnutrition for patients in the community. These patients live in their own homes and are visited by members of the community team at regular intervals. Many are older, with multiple conditions including dementia, and as a result are at risk of undernutrition. Current team policy requires patients to be screened at monthly intervals using a clinical assessment tool, results of which are recorded and used to monitor nutritional health, and if necessary develop care plans for malnutrition.

Because of the distributed nature of visits, HCPs have hitherto recorded results of these screening assessments within a paper record. However, there is some concern that these paper records may not easily be integrated into team discussions of care planning (e.g. because the paper records are not always readily available). In order to address this, the team are now implementing an electronic system to record screening results, and retrieve them for team discussion and care planning.

Intervention: the team already use an electronic patient record system for most of the information regarding patient treatment and care, and the intervention updates this system to include a nutritional care component. Screening is performed on home visits by HCPs, who then enter the results into electronic record system. These records are then retrieved by team leaders and presented for discussion at team meetings, and where necessary care plans are agreed. These care plans are then entered into the system by team administrators who are present at the meetings and retrieved by HCPs prior to their next visit with the patient (care plans are integrated into patient information retrieval processes that already exist within the team). Outcome measures for success of the new system include numbers of patients screened (compared with previous years using the paper record), and changes in nutritional health of patients identified as being at risk of undernutrition.

Context: The community care team operates in a highly distributed fashion. Typically, HCPs will begin their shift by visiting the team base to retrieve patient records, after which they will begin their home visits. The work involves a range of patients with diverse needs and capacities, meaning that working conditions are variable and can be highly unpredictable, for example, a routine visit may uncover urgent care issues requiring immediate attention, reducing time for visits to other patients and increasing pressure on the individual HCP. Team meetings at which care planning takes place are also subject to time pressure. These may only last 30 minutes, during which 10 patients may be discussed, before HCPs are required to begin visits.

The intervention stems from concerns among managers and senior HCPs that this changeable working context often leads nutritional work to fall down the list of priorities, and that paper records of screening are vulnerable to exclusion from team care planning discussions because they aren't stored in one place. In addition, embedding retrieval of nutritional care information within the existing patient records system was intended to reduce the time taken to source material for discussion, and reduce the likelihood that such information would be absent from care planning discussions.

Aim: The aim of this exercise is to identify questions that can be used to inform prospective planning and/or ongoing evaluation of implementation (readers are invited to explore one or both kinds of application depending on their interest). In both cases, the objective will be to identify factors that may promote or hinder implementation and longer-term embedding in routine practice, of the nutritional component of the electronic patient record system.

3.2. Generating research questions using NPT.

Construct	Construct description	Component	Topic of investigation	Planning questions	Evaluation questions
Coherence	*The sense-making work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices.*	**Differentiation**	To understand how agents understand that a set of practices and their objects are different from each other.	How will information provided by the implementation team help HCPs distinguish the new procedure from current working practices?	Do community HCPs see the new procedure as different from existing ways of working, and if so how?
		Communal specification	Sense-making relies on people working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practices		
		Individual specification	Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around a set of practices.		
		Internalisation	Sense-making involves people in work that is about understanding the value, benefits and importance of a set of practices.		

Figure 3. Worked example use of NPT in nutrition screening and care planning scenario.

In Figure 3, we can see how a table might be used to identify questions relevant to the *Coherence* domain of NPT (see also Appendix). Note that wording of questions preserves the emphasis on *action*; for example, the planning question linked to the *Differentiation* component reads: '***How*** will information provided by the implementation team help HCPs distinguish the new procedure from current working practices?'. The 'how' is important here because while procedural differences between the two may seem obvious, it is possible that participants may interpret this process as a different way of doing the same thing (that is, they may not immediately see the benefits that those developing the intervention have in mind). Accounting for *how* these differences are made visible thus relates to an important part of the work necessary for successful implementation. For example, Ross et al's experience of implementing the *HeLP-Diabetes* intervention (discussed in section 2.1) indicates that discussions with HCPs, in addition to written information sources, were important in identifying and addressing questions about how the new procedure differed from existing practice [11]. Focus on action is also preserved in the example evaluation question (also linked to *Differentiation*): 'Do community HCPs see the new procedure as different from existing ways of working, and if so ***how***?' (see Figure 3). In both planning and evaluation, framing of the question will also affect further discussions about methods (i.e. a focus purely on belief or sentiment may suggest methods, such as attitudinal surveys using scale measures, that fail to capture processes relevant to understanding implementation which may better be investigated by, for example, interviews or in-person observations).

3.3. Next steps and concluding remarks

We now invite readers to continue with the example, by adding their own questions in the right-hand columns of the blank table (see Appendix). You may choose to do this for select components, or all of them[4] – or you may use the table to think through a different scenario of your own choosing.

Before concluding with some questions about method, it may also be helpful to note the use of this table in communicating the NPT framework to others involved in an implementation planning or evaluation project. Implementation projects can involve a range of professional groups, conventions, and languages which means that familiar examples may be helpful in building shared understanding of the general principles of NPT. Taking the example questions in the right-hand columns of figure 3, we can see how reading from the left-most column to this question links the component, construct, and context specific question. We can therefore also see that reading in the reverse direction offers an opportunity for communicating NPT principles using questions rooted in contexts that may be more familiar to some participants. This may be helpful in building a shared understanding of the framework – of implementing the implementation study itself.

Having derived research questions, the next step would be to consider research methods through which to conduct these investigations. Detailed discussion of the wide range of potential methods is beyond the scope of this chapter, and readers may look to the systematic review cited at the beginning of this section for a more detailed overview [1]. For those who may be implementing health informatics interventions, but be unfamiliar with process evaluations in general, this may provide a useful introduction to methods (particularly those involving qualitative observation) that have been used effectively in previous projects but may not feature commonly in other evaluations of health informatics systems.

References

[1] C.R. May, A. Cummings, M. Girling, M. Bracher, F.S. Mair, C.M. May, E. Murray, M. Myall, T. Rapley, and T. Finch, Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review, *Implement. Sci.* **13** (2018) 80. doi:10.1186/s13012-018-0758-1.

[2] C. May, and T. Finch, Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory, *Sociology*. **43** (2009) 535–554. doi:10.1177/0038038509103208.

[3] C. May, T. Rapley, F.S. Mair, S. Treweek, E. Murray, L. Ballini, A. Macfarlane, M. Girling, and T.L. Finch, Normalization Process Theory On-line Users' Manual, Toolkit and NoMAD instrument, (2015). http://www.normalizationprocess.org.

[4] NHS Highland, Infection Control is everyone's responsibility, (2013). http://www.nhshighland.scot.nhs.uk/News/Pages/InfectionControliseveryone'sresponsibility.aspx (accessed November 18, 2018).

[5] Cheshire and Wirral Partnership NHS Foundation Trust, Safeguarding children is everyone's responsibility, 2017. http://www.cwp.nhs.uk/media/2040/safeguarding-children-is-everyoness-responsibility.pdf.

[6] Information Governance Alliance (IGA), Information Governance is the responsibility of everyone, 2015. https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga/information-governance-resources/new-resource-consultations/new-publications-closed-consultations/informatio.

[4] For further reference, readers may view a fully completed version of this table applied to an evaluation study of a nutritional care intervention (see Additional File 2 [17])

[7] T.L. Finch, F.S. Mair, and C.R. May, Teledermatology in the U.K.: lessons in service innovation, *Br. J. Dermatol.* **156** (2007) 521–527. doi:10.1111/j.1365-2133.2006.07608.x.

[8] T. Karagiannis, A. Liakos, M.E. Branda, E. Athanasiadou, M. Mainou, P. Boura, D.G. Goulis, A. LeBlanc, V.M. Montori, and A. Tsapas, Use of the Diabetes Medication Choice Decision Aid in patients with type 2 diabetes in Greece: A cluster randomised trial, *BMJ Open*. **6** (2016) 1–10. doi:10.1136/bmjopen-2016-012185.

[9] M.J. Johnson, and C.R. May, Promoting professional behaviour change in healthcare: What interventions work, and why? A theory-led overview of systematic reviews, *BMJ Open*. **5** (2015). doi:10.1136/bmjopen-2015-008592.

[10] J. Ross, F. Stevenson, C. Dack, K. Pal, C. May, S. Michie, S. Parrott, and E. Murray, Evaluating the implementation of HeLP-Diabetes within NHS services: Study protocol, *BMC Health Serv. Res.* **14** (2014) 1–8. doi:10.1186/1472-6963-14-51.

[11] J. Ross, F. Stevenson, C. Dack, K. Pal, C. May, S. Michie, M. Barnard, and E. Murray, Developing an implementation strategy for a digital health intervention: an example in routine healthcare, *BMC Health Serv. Res.* **18** (2018) 794. doi:10.1186/s12913-018-3615-7.

[12] M.-M. Bouamrane, and F.S. Mair, A study of clinical and information management processes in the surgical pre-assessment clinic, *BMC Med. Inform. Decis. Mak.* **14** (2014) 22. doi:10.1186/1472-6947-14-22.

[13] D.J. Clarke, M. Godfrey, R. Hawkins, E. Sadler, G. Harding, A. Forster, C. McKevitt, J. Dickerson, and A. Farrin, Implementing a training intervention to support caregivers after stroke: A process evaluation examining the initiation and embedding of programme change, *Implement. Sci.* **8** (2013) 96. doi:10.1186/1748-5908-8-96.

[14] C. May, Towards a general theory of implementation, *Implement. Sci.* **8** (2013) 18. doi:10.1186/1748-5908-8-18.

[15] M.J. Johnson, A.A. Leaf, and F. Pearson, Successfully implementing and embedding guidelines to improve the nutrition and growth of preterm infants in neonatal intensive care: a prospective interventional study, *BMJ Open*. (2017). doi:doi:10.1136/bmjopen-2017-017727.

[16] J.C. Moullin, D. Sabater-Hernández, F. Fernandez-Llimos, and S.I. Benrimoj, A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework, *Heal. Res. Policy Syst.* **13** (2015) 1–11. doi:10.1186/s12961-015-0005-z.

[17] M. Bracher, J. Murphy, K. Steward, K. Wallis, and C.R. May, What factors promote or inhibit implementation of a new procedure for screening and treatment of malnutrition in community settings? A prospective process evaluation of the *Implementing Nutrition Screening in Community Care for Older People* (INSCCO, *BMJ Open*. **9** (2019) e023362. doi:10.1136/bmjopen-2018-023362.

Appendix – Identification tables for questions relating to planning and/or evaluation of a complex healthcare intervention using NPT.

Construct	Construct description	Component	Topic of investigation	Planning questions	Evaluation questions
Coherence	*The sense-making work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices.*	**Differentiation**	To understand how agents understand that a set of practices and their objects are different from each other.		
		Communal specification	Sense-making relies on people working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practices		
		Individual specification	Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around a set of practices.		
		Internalisation	Sense-making involves people in work that is about understanding the value, benefits and importance of a set of practices.		
Cognitive Participation	*Cognitive Participation is the relational work that people do to build and sustain a community of practice around a new technology or complex intervention.*	**Initiation**	When a set of practices is new or modified, a core problem is whether or not key participants are working to drive them forward.		
		Enrolment	Participants may need to organize or reorganize themselves and others in order to collectively contribute to the work involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things.		
		Legitimation	An important component of relational work around participation is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.		
		Activation	Once it is underway, participants need to collectively define the actions and procedures needed to sustain a practice and to stay involved.		

Construct	Construct description	Component	Topic of investigation	Planning questions	Evaluation questions
Collective Action	*Collective Action is the operational work that people do to enact a set of practices, whether these represent a new technology or complex healthcare intervention.*	**Interactional Workability**	This refers to the interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings.		
		Relational Integration	Knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them.		
		Skill set Workability	Allocation work that underpins the division of labour that is built up around a set of practices as they are operationalized in the real world.		
		Contextual Integration	Resource work - managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures.		
Reflexive Monitoring	*Reflexive Monitoring is the appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them.*	**Systematisation**	Participants in any set of practices may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting information in a variety of ways.		
		Communal appraisal	Participants work together - sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of a set of practices. They may use many different means to do this drawing on a variety of experiential and systematized information.		
		Individual appraisal **Reconfiguration**	Participants in a new set of practices also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions. Appraisal work by individuals or groups may lead to attempts to redefine procedures or modify practices - and even to change the shape of a new technology itself.		