

# An introduction to Implementation Science and Normalization Process Theory

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15<sup>th</sup> November 2016

*'Experience without theory is blind' (Immanuel Kant, 1724 – 1804)*

## Introduction

This chapter begins by introducing Implementation Science and summarizing the different models, frameworks and theories of change in health care, with specific reference to Normalization Process Theory (NPT). Next, the main constructs, components and potential utility of NPT are described and illustrated with a small selection of practical examples.

## Implementation Science

Conducting rigorous research, building a sound evidence base to inform high-quality care and designing and developing useful interventions, methods or tools for complex health care settings are all challenging tasks. However, successfully disseminating this evidence into practice or implementing an intervention and ensuring it is used long enough to become embedded into routine care processes are arguably even greater challenges. In fact, there are often 'translational gaps' (1) as much research and many interventions are never implemented at all, or only partially adopted or not sustained despite their potential utility. This is true across health care, but a particular exemplar in respect of quality and safety initiatives. (2) As a result, precious time and resources are often squandered on unsuccessful projects while the alluring promise of efficiency and quality gains remain unfulfilled.

Unsurprisingly, researchers and policy makers are very keen to avoid this waste and are interested in identifying the facilitators of improvement initiatives and overcoming the multiple barriers to the transfer of knowledge and build research-policy-practice links. (3) Implementation science was borne out of this desire and is defined as the scientific study of methods to promote the systematic uptake of research findings and other evidence based practices into routine practice to improve the quality and effectiveness of health services and care. (4) A more practical description of this 'relatively young science' (5) is that it aims to open the 'black box of change'. (6).

Our current knowledge about implementation is rooted in the disciplines of sociology and psychology and dates back more than half a century. Over the years a diverse range of implementation models, frameworks and theories have been developed and proposed offering researchers a rich selection to choose from. However, much of the early research in health care was empirically driven without consideration of the theoretical underpinnings of implementation.



This has been likened to ‘an expensive version of trial-and-error’ and made it difficult to understand or explain how and why interventions fail or succeed, or to identify the determining factors of successful implementation efforts. (7) There are at least two main reasons why explicit theoretical underpinnings are desirable for designing and implementing interventions. First, theory provides a generalizable framework enabling comparison of effectiveness of interventions in different contexts and settings and opportunities for incremental accumulation of knowledge. Second, there are almost always multiple factors at different levels that determine health care outcomes. Applying theoretical frameworks may help to reduce the risk of important determining factors being overlooked. (6).

Seeking to address this ‘theoretical vacuum’ (8) in studies’ intervention designs, the MRC issued guidelines which strongly recommend the explicit and active application of implementation theory in order to proactively enhance transfer of research findings into clinical practice. (9) The implications of the MRC recommendations are that researchers and policy makers should aim to: establish the nature of associations between an intervention and observed outcomes; recognize the potential interactions between an intervention and the setting in which it is introduced; and consider the mechanisms through which the intervention and interactions improve care or conversely fail to improve care. In other words, determining whether and to what extent new methods, tools, guidelines or interventions are successful in particular health care settings requires that the factors hindering and facilitating their implementation be identified and understood. These necessary processes are greatly facilitated by judiciously selecting and applying appropriate models, frameworks and theories from which interventions’ main determining factors can be derived and/or described. (6).

Before we consider the potential options, it is necessary to first define four common terms in this chapter: theory; model; framework; and implementation. A common definition of ‘theory’ is a system (or set) of analytical ideas, principles or statements held as an *explanation* or account of a group of facts or phenomena. (10, 11) The terms ‘models’ and ‘frameworks’ are often and inappropriately used interchangeably with ‘theories’. Models are deliberate simplifications of phenomena and are descriptive, but not explanatory. Frameworks consists of descriptive categories that provide outlines, structures or overviews of the concepts, constructs and variables that presumably give rise to specific phenomena but without explanations. (12) ‘Implementation’ is defined and understood for the purposes of this study as ‘the process of putting to use or integrating new practices within a setting’. (12) It is part of a diffusion-dissemination-implementation continuum, but should be differentiated from these related terms. Diffusion refers to the passive, untargeted and unplanned spread of new practices, while dissemination implies the active spread of new practices to a target audience using specific strategies.



## Models, frameworks and theories of change in health care

A review in 2004 of the available theories relating to innovation in health care at that time concluded that the literature was complex, diverse and large and articulates the challenge of describing and understanding change as the product of multiple, unpredictable interactions between interventions, specific contexts and settings. (13) The different theories, models and frameworks of change in health care can be classified into five different groups, depending on whether their main focus is on: (i) stages of change; (ii) individuals; (iii) social contexts; (iv) organisations; or (v) political and economical contexts. (6).

From the perspective of the 'stages-of-change' models and theories, change happens as a result of individuals and teams taking 'steps' to progress through consecutive stages. Each stage is characterized by different determining factors and therefore requires unique strategies for change. This allows distinguishing subgroups or segments. In Roger's innovation-diffusion theory there are: innovators; early adopters; early majority; late majority; and laggards (14) while the stage-of-readiness-to-change model describes levels of motivation by distinguishing between: precontemplation; contemplation; preparation; action; maintenance; and completion. (15).

The different theoretical approaches focussing on individuals as the main agents of change can be further subdivided into cognitive, educational and motivational theories.

- **Cognitive theories:** Rational decision-making theories assume the behaviour of clinicians are the result of considering evidence and balancing the relative advantages and disadvantages of different choices in an objective and impartial manner. In reality, many clinicians' decisions are not rational but based on contextual information, previous experience and cognitive structures – so called 'illness scripts'. (16)
- **Educational theories:** Adult learning theories state people are more motivated to change problems they identify than those that are presented to them. On the other hand, clinicians have different learning styles (e.g. activist; reflective; theoretical; and pragmatic (17)), not all have the inclination or competence for self-directed learning and self-assessment is notoriously challenging (18).
- **Motivational theories:** The theory of planned behaviour states behaviour is influenced by intentions, and intentions are in turn influenced by perceptions of social norms (e.g. peers), self-efficacy (e.g. perceived control in relation to the behaviour) and the individuals' attitudes. (19) Attitudes are determined by the expected outcomes of the behaviour and the clinicians' appraisal of these outcomes.

From a social context perspective, there are models and theories of communication (e.g. the persuasion-communication model; elaboration likelihood model; and heuristic systematic model), professional development and leadership, social network and influence theories and social learning



theories. The different types of theories focusing on organisations include: theories of organisational culture and integrated care, organisational learning culture, complexity theory and the theory of quality management. Finally, examples of theories with an economical/political focus include reimbursement theories and the theory of contracting.

An alternative taxonomy with five categories was recently proposed based on the application of the different types of models, frameworks and theories in implementation science. The categories are: (i) process models; (ii) determinant frameworks; (iii) classic theories; (iv) implementation theories; and (v) evaluation frameworks. (12) However, the author acknowledges that there is considerable overlap between categories. For example, while implementation theories typically explain phenomena, they may also be used to describe (e.g. function as 'process models' and evaluate.

Taxonomies of models, frameworks and theories are interesting and satisfying from a scientific perspective, as is recognizing and applying specific 'labels' to individual implementation approaches. However, there is a more important and serious rationale for this explicit differentiation, which is the acknowledgement that models, frameworks and theories all have different assumptions, aims and characteristics which strongly influence their potential relevance and usefulness for specific research designs.

A third and admittedly oversimplified taxonomy of the different theories, models and frameworks is therefore to categorize them into one of two main groups depending on whether they consider implementation as the product of 'institutionalization' or 'individual action'. (20) 'Institutionalization' theories are those with the theoretical perspective whereby implementation is understood as the product of organisational activity. From this perspective, the 'actors' and 'contexts' are considered to interact in predictable and rational manner during implementation processes. In contrast to 'institutionalization', theories with an 'individualized' perspective describe implementation and implementation outcomes from the perspective of the 'actors'. A central assumption of these theories is that individuals have 'free will' and actively choose to implement an intervention (or not). Current evidence supports this perspective - at least to a degree - with a general consensus that 'individual' factors are indeed important determinants of successful implementation, but that they only account for an estimated quarter of the observed outcomes.

Several decades of research and the anecdotal experience of many clinicians strongly suggest that, while these two perspectives of implementation are helpful, neither fully describe or 'capture' the complexities of developing, successfully implementing and evaluating complex health care interventions. Organisational innovations and new health care interventions are often imposed and individuals and teams have to work creatively to flexibly configure their existing practices to accommodate the changes according to their own specific requirements and local contexts. If there are workability issues with an intervention that they cannot resolve it leads to problems with integration. The majority of models, frameworks and theories also only describe and explain



implementation processes retrospectively, which limits their potential utility, e.g. they lack predictive power.

Given the relative limitations of existing theoretical perspectives about implementation, the need for a new and different theory of implementation became apparent that can mediate between macro (e.g. diffusion, institutionalization and organisational level factors) and micro (cognitive and individual action) levels of analysis. (21) In response, the Normalization Process Theory (NPT) was developed. While there are many similarities between NPT and other, existing theories, NPT expands our understanding of implementation by offering a third potential perspective: successful implementation is the product of the 'work' health care staff have to do individually and collectively to implement research, a new method or a complex health care intervention. NPT is described in more detail below.

### Normalization Process Theory (NPT)

The Normalization Process Model (NPM) was developed and validated while conducting telemedicine and chronic disease management research in UK primary care settings in order to enable the effective analysis of the qualitative data collected in multiple studies between 1995 and 2005. (22) The model is conceptual and rational and consists of four components that allow barriers and facilitators to the implementation of complex healthcare interventions to be identified, described and evaluated but does not offer instructions about 'how' to do normalization. Innovation and change are recognized as often arising from external sources or being imported into local contexts but, because the departing point of the model is 'normalization', the focus is on the 'creativity imbued in everyday professional work'. (21).

The NPM was subsequently developed into the Normalization Process Theory (NPT). (1, 20, 23) The most significant changes to the model were grouping the four original components together as a single construct – 'collective action' – and then adding three additional constructs. (23) NPT is a formal and verifiable theory with the purpose of empirical application rather than abstract critique. It is defined as an '*explanatory framework for investigation the routine embedding of material practices in social contexts*'. (20) Material practices are all of the things people do when they implement complex health care interventions. (3) NPT is a middle-range theory of social action. Theories are considered 'high', 'middle' or 'low' depending on their place in an abstraction level continuum. The 'high' level theories have a universal or almost unlimited scope of application, while 'middle' level theories explain limited sets of phenomena. (11) There is currently no 'high' level theory of implementation. It is possible in some disciplines to build a higher level theory from lower abstraction level theories (analogous to building a wall from bricks). While a general theory of implementation has recently been proposed (24) the general consensus is that it is very unlikely there will ever be a grand theory of implementation because implementation is too multifaceted and complex to allow universal explanations. (12).



NPT is a theory about the 'work' people do collectively and as individuals to implement and sustain an intervention. From this perspective, 'work' is defined as 'purposive social action that involves the investment of personal and group resources to achieve goals.' (20) In other words, NPT is concerned with understanding 'what people do rather than their attitudes or beliefs'.

The term 'normalization' is defined as the embedding of a technique, technology or organisational change as a routine and taken-for-granted element of clinical practice. (21) It includes all of the stages from design, development and testing of an intervention, through to its implementation, embedding and finally integration. (20) Normalization should be differentiated from adoption (e.g. an intervention is accepted and is used from time to time) and rejection (e.g. an intervention is spurned). Just because some innovations and interventions become normalized do not necessarily imply that they were effective in achieving their intended outcomes, nor that they are of high quality or that they are permanent, e.g. they may become de-normalized with time. (22) The converse is also true – an intervention may be useful and meet the organisational criteria for 'successes and yet not become normalized. (25) This is reason why 'proof of concept' studies add little value to the evidence base in implementation science and are unlikely to do so. (26, 27) Despite this conceptual problem much research still focuses on 'can it work/does it work?' questions rather than asking 'how' interventions should be implemented.

## NPT constructs and components

The different types of implementation work are described and categorized according to four main interactive constructs termed: coherence; cognitive participation; collective action; and reflexive monitoring. NPT postulates that for evidence and innovation to become routine practice ('normalized'), work has to be done to understand and organise the method (coherence), staff have to be enrolled into using it (cognitive participation), the method has to be enacted (collective action) and work has to be done to organise, collect and interpret data about the method's effects (reflexive monitoring). (20).

The four main constructs are characterised by specific types of 'investments' required from implementers, without which successful normalization becomes highly unlikely. Each construct is further divided into four 'components', which allows the specific nature of the work to be described in more detail. The components have been referred to as 'generative mechanisms' because aggregating the different and specific 'work'/tasks produces the outcomes from implementing an intervention. Finally, each component may be subdivided even further, if it is deemed necessary for the study, in order to differentiate between work that is 'immediate' or 'organizing'. (20).

Although the constructs and components describe different types of 'work', they are highly correlated, 'fluid and dynamic' (20) and exists concurrently. In practical terms, this means that constructs and components constantly 'interact' with the potential to influence and change each



other. The relative importance of each of the constructs and components fluctuate over the implementation period but also ‘between particular empirical contexts’. A simple analogy of NPT would be that ‘components’ are atoms and ‘constructs’ are molecules. Just as atoms and molecules may potentially interact, influence each other to varying degrees and change over time, the constructs and components affect each other and are also affected by external factors. An example would be the work of ‘enrolment’ of staff and ‘initiation’ of a project which are clearly related in a practical and temporal sense. Once the project is established, these tasks become less important.

The main constructs and all of their components are described in more detail below. (1, 20, 23).

### **Construct: Coherence**

Coherence (CO) is the *work* individuals and teams have to do in order for them to *make sense of* an intervention (other synonyms include: ‘understanding’, ‘defining’, ‘forming’, ‘holding together’, ‘mobilizing’, ‘conceptualizing’ and ‘organizing’). In other words, they need to create ‘a cognitive and behavioural ensemble’ of the intervention. (20) In practical terms this means working to ‘package’ the solution or change so it becomes a unique and recognizable entity that can ‘stick’ within specific contexts. Participants’ understanding typically increases and evolves over time and requires them to *invest meaning*. Coherence has four components: differentiation; individual specification; communal specification; and internalization.

#### ***Differentiation***

Differentiation (DI) is the work participants do to understand the *differences and similarities* between the proposed method, tool or intervention and their existing methods, tools and practices.

#### ***Communal specification***

Communal specification (CS) is the required work to understand the *purpose* of the intervention. In other words, what is the change or solution’s likely value for each of them individually, for the HHS and for their patients? Participants’ understanding of the aims and benefits may be different from the intervention’s intended aims and benefits. If this difference is small, there is a ‘high degree’ of ‘communal specification’, which is desirable as it helps to facilitate normalization.

#### ***Individual specification***

Individual specification (IS) is the work of considering and quantifying the expected ‘effort’, time and resources that will be required to successfully implement the intervention, and how this could best be done. In other words, how feasible would it be to implement the change/solution? While a sound understanding of the task requirements are important, it does not necessarily mean that the resources or appropriately skilled, trained and experienced staff are available or willing to participate. Allocating adequate resources and effectively engaging clinicians in the project requires additional work of ‘skill set workability’ (discussed later).



## **Internalisation**

Internalisation (IT) describes the work participants do to understand and interpret the intervention or change in relation to their own principles and beliefs and also the prevailing culture in their team or organisation. It includes the work they have to do to interpret the findings from the implementing the change/solution to their own contexts and whether they decide to take further.

## **Construct: Cognitive participation**

The cognitive participation (CP) construct describes the relational work that is required to *build and sustain a community of practice* around an intervention and requires participants to invest 'commitment'. This involves identifying *who* should be involved with the change, *recruiting* and organizing them and keeping them *engaged* throughout the implementation process. CP's four components are: initiation, enrolment, activation and legitimization.

### **Initiation**

Initiation (IN) is the initial work of successfully 'bringing forth' an intervention. It is usually performed by key participants who are capable of 'driving forward' an intervention. Examples of initiation work include promoting and raising awareness of the solution and planning and delivering educational events.

### **Enrolment**

Enrolment (EN) is the work of recruiting participants who will implement the intervention and keeping them engaged in the process. In other words, EN describes *who is involved* with the solution and when, in what capacity and to what degree they contributed. However, the work of determining *who* should be involved in implementing the change is described by the 'skill set workability' component.

### **Activation**

The activation (AC) component describes the *continuing support* work that is necessary to sustain the use of an intervention. For this work to be successful, participants need to remain actively involved in the process. This, in turn, depends on whether they feel 'empowered' to enact change and they consider ongoing participation as 'right' for them (the work of Legitimation – see below).

### **Legitimation**

Legitimation (LE) is the work clinicians and general practice staff have to do, but also the work of policy makers and professional organisations, in order to legitimize and justify their involvement with the change.



## **Construct: Collective action**

Collective action (CA) is the operational work required to *enact* the solution or change and requires participants to invest *effort*. The CA construct describes the organisational, external, immediate and internal factors that may hinder or facilitate the implementation process. The four components of CA are: interactional workability, relational integration, skill-set workability and contextual integration.

### ***Interactional workability***

Interactional workability (IW) is the work of applying the change in practice – e.g. to ‘operationalize’ it. It is important to consider whether informal work-place rules may be affecting this work, and if the intervention helps or hinders clinicians’ ‘normal’ work. The IW component includes the actual time and effort the work required, whereas participants’ perceptions of the time and effort they invested is described by the ‘individual specification’ component.

### ***Relational integration***

Relational integration (RI) is the work of building and maintaining *confidence*, trust and *accountability* in an intervention and in each other’s ability to successfully implement it. In other words, RI is the work of incorporating a change within existing relationships. This component should be differentiated from the work of ‘legitimation’. One way in which the work can be differentiated, is that Legitimation work usually involve external parties.

### ***Skill-set workability***

The Skill-set workability (SW) component describes the work of *dividing and* allocating resources so that an intervention can successfully be implemented. This requires division of labour, e.g. ‘who does what?’ The SW component also includes the work of deciding who has the ‘power’ to make the decisions about resource allocation and work delegation. To be effective, skill-set workability requires consideration of the knowledge, skills, attitudes and capacity of staff.

### ***Contextual integration***

Contextual integration (CI) is the work of integrating the intervention into existing structures and contexts. In addition, there is work to incorporate the change within the prevailing organisational culture (work that is shared with the ‘initiation’ component) and professional roles (work that is shared with the relational integration component). The work of CI depends on the availability of adequate and appropriate resources and therefore also includes: provision of new resources or re-allocating existing *resources*; senior leadership support; restructuring current *policies* and *infrastructure*.



## **Construct: Reflexive monitoring**

Reflexive monitoring (RM) is the work of *assessing* the individual and communal worth of the intervention. It has been defined as: ‘the work of understanding and evaluating a complex intervention in practice’ (28) and requires participants to invest ‘comprehension’. This work requires adequate time, reliable metrics and sharing of results. The four components of RM are: systematisation, individual appraisal, communal appraisal and reconfiguration.

### ***Systematisation***

Systematization (SY) is the work of collecting and organizing adequate and reliable data about the intervention or change to enable evaluation. This work is normally undertaken through a combination of formal and informal methods. This component is therefore also concerned with the methodological formality with which implementers derive value-judgements about the intervention’s usefulness.

### ***Individual appraisal***

The *Individual appraisal (IA)* component describes the work participants do to evaluate the intervention’s worth for *them*, e.g. the clinician reviewer, the reviewer’s practice team and their patients. IA is typically informed by data derived from informal methods and relies on ‘experiential and unsystematic practices of judging the value and outcomes of practice’.

### ***Communal appraisal***

This component describes the work of participants to evaluate the intervention’s worth to *others*, e.g. clinicians, practices and specific professional and patient groups other than their own. Communal appraisal is typically informed by data derived from formal methods (at least in comparison with IA).

### ***Reconfiguration***

Reconfiguration (RE) is the work participants do to *modify* the intervention, themselves (e.g. their attitudes, skills, knowledge, tasks) or their contexts (practice procedures, policies and infrastructure).

## **The rational for selecting a NPT framework for implementing change**

NPT has at least three important ‘strengths’ which help justify its selection as a study design. First, it was developed with methodological rigour, its design process was transparent and it was subsequently validated through practical application in ‘real life’ health care settings. Second, because NPT is about ‘workability in practice’ (28) it can be applied iteratively to study temporal changes in perceptions, actions and outcomes. Third, it is transferable to different healthcare settings and can be applied to a wide range of innovations, methods, tools and interventions. Even though NPT is relatively ‘young’ in research terms – it was developed only a decade ago - it has already been successfully used in multiple studies and settings.



In the UK, NPT has been used to study the implementation of nutrition guidelines for elderly patients in residential care homes (29), to evaluate the integration of telecare management of chronic diseases in the community (27, 30), as a framework for generating and analysing data relating to the management of early chronic kidney disease in primary care (31) and to assess the treatment burden among patients with chronic heart failure in general practice. (32) In Australia the barriers and enablers to initiating insulin in primary care were identified (33) and a conceptual NPT framework was used to design a new model of depression care in general practice and study its effective implementation. (34) A similar approach was adopted in the Netherlands to implement a stepped-care approach to the management of depression in primary care. (35) Finally, NPM was used in South Africa to analyse provider experiences of a new tuberculosis treatment programme (36) and a provider-initiated HIV testing and counselling intervention. (37).

This small selection of studies help to demonstrate some of NPT's multiple potential applications. Its main uses so far has been as a validated conceptual framework for *describing, understanding* and *evaluating* complex health care interventions. However, it can and has been used to help design, develop and test complex interventions and to optimize trial parameters. In this way, NPT allows implementers to focus through a socio-technical lens on areas likely to be problematic and direct their efforts accordingly. (1) Another important application is to help 'bridge the translational gap' between research and innovation and their practical implementation by 'identifying possible barriers and facilitators' to these processes. (3).

While post-hoc explanations and interpretations of events are important, an 'ideal' theory overcomes the 'significant methodological and theoretical challenge' inherent in predicting future outcomes with at least a modicum of reliability and success. This holds true in the field of implementation science because, no matter how complex and emergent implementation processes may appear, they are subject to normative and structural constraints which are usually not arbitrary. Consequently, the 'trajectory of a practice can be anticipated within certain limits' which in turn enables 'prospectively assessing the potential of practices to normalize' an intervention. (20) In other words, NPT can be applied to determine the more likely outcomes of an intervention, e.g. whether it will be successfully normalized or not. At the very least, NPT can be applied to '*judge the implementation potential*' of an intervention. The practical implication is that NPT may therefore have utility as a potential 'trial killer'. (1, 28) Applying the NPT framework to a study proposal would help to determine the likelihood of that intervention being successfully normalized, and hence whether it is worthwhile to proceed with the study (or not). (3).



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