

## **BUILDING AN INTERDISCIPLINARY THEORY OF IMPLEMENTATION, EMBEDDING, AND INTEGRATION: THE DEVELOPMENT OF NORMALIZATION PROCESS THEORY**

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## **ABSTRACT**

### **Background**

Theories are important tools in the social and clinical sciences. The methods by which they are derived are rarely described and discussed. Normalization Process Theory explains how new technologies, ways of acting, and ways of working become routinely embedded in everyday practice and has applications in the study of implementation processes. This paper describes the process by which it was built.

### **Methods**

Between 1998 and 2008, we undertook three tasks. (i) We derived a set of empirical generalizations from analysis of data collected in qualitative studies of healthcare work and organization. (ii) We developed an applied theoretical model through summative analysis of empirical generalizations. (iii) We built a formal theory through a process of extension and implication analysis of the applied theoretical model.

### **Results**

Each phase of theory development showed that the constructs of the theory did not conflict with each other, had explanatory power, and possessed sufficient robustness for formal testing. As the theory developed its scope expanded from a set of observed regularities in data with procedural explanations, to an applied theoretical model, to a formal middle-range theory.

### **Conclusion**

Normalization Process Theory has been developed through procedures that were properly sceptical and critical, and which were opened to review at each stage of development. The theory has been shown to be sufficiently robust to merit formal testing.

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## **BACKGROUND**

Theories are important for the sciences, social and natural, because they make possible robust explanations of previously or currently observed phenomena, and because they are points of departure for forecasts about hypothesised or future phenomena. This paper describes the procedures that were used to develop a theory of the implementation, embedding and integration of material practices in their organizational contexts—Normalization Process Theory [1].

Normalization Process Theory may prove to be useful in understanding the routine embedding of new ways of working and organizing work in health care and other fields of practice. The objective of this paper is to describe the procedures by which the theory was built. We show how these procedures led to a set of propositions that were regarded as possessing sufficient face validity and conceptual robustness to warrant formal testing. That work is currently underway and its results will be reported in due course.

The purpose of the paper, then, is to offer a procedural account of the work that has led from the production of a set of empirical generalizations (robust observations awaiting theoretical explanation); to the development of an applied theoretical model (analytic propositions that define and explain a limited set of phenomena encountered in a specific domain); to a general theory (analytic propositions that define phenomena, identify and explain the mechanisms by which they come about, and describe the causal investments that drive those phenomena). )

Presenting a procedural account of this work is useful because theories often seem to emerge into the world fully formed with little or no account of where they came from, or by which methods they were derived. The Normalization Process Theory did not emerge fully formed; its development has included changes in scope as well as method. We doubt that this is unusual in theory development. By providing this account of what happened during the development of the Normalization Process Theory, we aim to support both transparency and facilitate meaningful and informed critique of the theory by others.

## **METHODS**

Building Normalization Process Theory comprised a highly collaborative set of tasks that grew organically over a period of ten years. What follows is a retrospective and procedural description of three phases of work:

- (i) The derivation of a set of empirical generalizations from analysis of data collected in qualitative studies of healthcare work and organization.

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- (ii) Constructing the *Normalization Process Model* (an applied theoretical model) through summative analysis of empirical generalizations.
  - (iii) Building *Normalization Process Theory* (a middle-range formal theory) through a process of extension and implication analysis of the applied theoretical model.

This account of the process of theory-building draws on two main resources. First, a collection of manuscripts of five papers [1-6], that includes almost all of their successive drafts and shows the development of the ideas discussed in this paper. Second, an archive of about 1300 emails and other correspondence since 2005 which record some of the informal discussions through which the work of theory-building described here was undertaken.

### **Phase 1: Developing empirical generalizations**

Between 1998 and 2002 a series of studies led to the development of a set of empirical generalizations [2, 7, 8] about the development and deployment of innovative health technologies in health care [2, 9]. These treated 'normalization' as the endpoint of an implementation process in which some new technology came to be routinely employed in service. The comparative synthetic methods used to generate empirical generalizations about telemedicine implementation processes were then used to perform a similar analysis on data collected in other studies. Three further synthetic analyses were performed using collaborative methods. These investigated: (i) the social organization of professional-patient relationships in the management of chronic illness in primary care [10]; (ii) the social construction and production of 'evidence in health care [8]; and (iii) the changing organization of clinical work around chronic illness in primary care [11]. The methods by which formative analyses were carried out have been described in detail elsewhere [3].

The empirical generalizations produced by these processes were general conclusions about regularities in the data, and were framed as formal propositions. They are given in **Box 1**. They did not in themselves make a theory because they were specific to particular contexts (i.e. although they were generalizations, they were not necessarily generalizable), and were not linked together by some account of causal relations, generative mechanisms, or organizing principles. In other words, they were observational rather than explanatory.

### **Phase 2: Building an applied theoretical model**

Between 2001 and 2006 the results of synthetic re-analyses of already collected data described above [2, 8, 10, 11] were subjected by CRM to a summative theory building process. Summative process led to a set of propositions (see **Box 2**) that were supported by rigorous data analysis. This aimed to develop what Stinchcombe [12] calls

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an *applied theoretical model* of the factors that promote or inhibit the *work* of routine embedding of some new health technology in practice. These were first subject to critical review from a large group of researchers to whom manuscripts of different iterations of the model were informally circulated, and discussed at a series of seminars. The product of this work was the *Normalization Process Model*, henceforth NPM [3, 13]),

The purpose of the NPM was to identify and explain those factors that promoted or inhibited Collective Action that led to the routine embedding of complex healthcare interventions in service settings. There were four of these (interactional workability; relational integration; skill-set workability; and contextual integration) and we defined these as the *constructs* of the NPM. At this stage the NPM was synthetic, drawing together the products of 26 different but related studies, and producing taxonomies, maps of relations between concepts, and generalizations [14]. These were linked together—as an applied theoretical model—by two kinds of conceptual apparatus, an explicit methodology for theory building, and broadly sociological explanations of the relations between its constructs, their dimensions, and components. Taken together these set the scene for possible empirical verification.

### ***Refining the Normalization Process Model***

As an applied theoretical model, the NPM was restricted to a specific field of activity [3]. To develop it further we sought to define and stabilise the way that we conceptualized theory itself. We assigned to theory three kinds of work [13]:

- *Accurate description.* A theory must provide a taxonomy or set of definitions that enable the identification, differentiation, and codification of the qualities and properties of cases and classes of phenomena. The analytic assertions and propositions developed in earlier synthetic analyses of qualitative data perform this function.
- *Systematic explanation.* A theory must provide an explanation of the form and significance of the causal and relational mechanisms at work in cases or classes of the phenomena defined by the theory, and should propose their relation to other phenomena.
- *Knowledge claims.* A theory must lead to knowledge claims. These may take the form of abstract explanations, analytic propositions, or experimental hypotheses. They may also map relations with other phenomena that are believed to possess similar qualities and properties.

Defining theory in this way enabled us to perform two additional and related tasks: (a) stabilising constructs of the NPM for use in practice; and (b) operationalizing a set of

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criteria to informally test its adequacy. The applied theoretical model then behaved as predicted, forming an basis for qualitative analysis of social processes implicated in routine embedding [5, 15-18].

### ***Road testing the Normalization Process Model***

Further development of the NPM involved a set of processes analogous to Implication Analysis like that proposed by Leiberson [19]. To do this we applied the NPM empirically, in a process of ‘road testing’ the theoretical model. This aimed to decide whether it was sufficiently plausible and robust to merit formal testing. This consisted of two main pieces of work.

- ***Qualitative data analysis.*** We integrated the NPM in qualitative data analysis in three large studies (of the implementation of ehealth technologies [20]; the integration of telecare systems [21, 22]; and the operationalization of a large randomized controlled trial). As we did this we sceptically sought evidence for the adequacy of the NPM to perform the three functions of theory—to define phenomena, explain mechanisms, and form knowledge claims. It is important to be clear that this was not formal testing, since we did not at this stage seek to falsify the NPM. Instead, we practically tested its usefulness as an analytic tool. We concluded that the model permitted the definition of a set of phenomena and provided limited explanations of the mechanisms that drove them. Qualitative data analysis revealed three key inadequacies in the NPM. It focused on factors that promoted and inhibited the work of enacting complex interventions but not on work that participants in those processes undertook to attribute meaning to, and monitor the outcomes of that work. It also did not account for the work that needed to be done to engage and inform participants in the work of enacting complex interventions.
- ***Research synthesis.*** Elwyn et al [6] undertook a parallel critical analysis of the NPM by applying it to the problems of operationalizing shared decision-making tools in medical consultations. Participants in that process mapped the constructs of the NPM against data from evaluation and other literature including primary studies and systematic reviews, and produced a set of attributions about the conclusions of these studies. The NPM was then applied to these attributions to determine whether it usefully explained them. Elwyn et al concluded that the NPM offered stable explanations of the collective work involved in shared decision-making processes and operationalizing decision-making tools. This process also drew attention to inadequacies of the NPM. It failed to account for the work through which participants made sense of shared decision-making tools, or the work of mutual engagement in shared decision-making processes.

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In the NPM, 'normalization' no longer formed the endpoint of an implementation process, but instead was conceived of as a social *process* with emergent outcomes. As an applied theoretical model, the NPM focused attention on volition and agency, rather than actor-networks, focusing attention on the *work* that must be done to operationalize and integrate some new form of practice, technique, technology, or organizational structure. It was clear, however that the NPM accounted only for problems of *enacting* complex interventions, and that enacting itself depended on work that enabled participants to make sense of, and engage with, the intervention. This recognition informed the next stage of theory-building.

### **Phase 3: Making a formal theory**

The NPM in its published form at the end of 2006 [3], was sufficient as a set of conceptual tools to analyse specific processes. 'Road testing' showed that it had utility in explaining factors that promoted and inhibited collective action in operationalizing practices. It did not, however, explain how practices were formed in ways that held together, how actors were enrolled into them, or how they were appraised. After 2006, we worked to solve these problems, and the NPM was extended into a middle range theory [23-25] that had face validity as an explanation for a set of general social phenomena.

The production of a formal theory is a quite different enterprise to the work that goes into the identification of empirical generalizations or applied explanations. The goal of theory-building at this level is to isolate the generic properties of phenomena and understand their operation [26]. To do this we had to reformulate the healthcare specific constructs of the NPM as generic or abstract propositions (that is, we decoupled them from the contexts from which they originated), and then to extend the theory by writing constructs that related to domains we had previously established were absent (coherence, cognitive participation and reflexive monitoring). Although at this stage we still regarded our work as framing an extended NPM, we had embarked on a process that would lead to a generalizable middle range *formal* theory.

1. We had defined NPM constructs as factors that promoted or inhibited collective action leading to the routine embedding of some intervention. We used additional analyses to identify macro-level analogues of the constructs of the model [22, 27]. These took the form shown in **Box 3**. We then constructed full definitions of the macro-level analogues of the NPM constructs and tested them against already collected data.
2. We operationalized macro-level constructs in a way that mapped on to the existing constructs of the NPM [28] (see **Box 4**). For example, we construed Collective Action as a macro-level construct (with micro-level constructs of

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- interactional workability; relational integration; skill-set workability; and contextual integration).
3. As we worked through macro-level constructs we also began to use a much more structured model of theory building in which generative mechanisms and relations required definition [29, 30]. In this context, we saw Coherence work not as a macro-level abstraction of contextual integration, but rather as a generative *mechanism* through which an intervention was subjected to sense-making procedures by its users. This led to us decoupling macro- from micro-level constructs and examining the components of generative mechanisms.
  4. We drew maps of the processes with which we were concerned. This method for identifying the constituents of conceptual models is called analytical theorizing by Turner [26]. This led to a map of the expanded NPM at work. We then followed Lieberson and Lynn [30] in converting macro-level constructs derived from the Normalization Process Model into descriptors of ‘generative principles.’

The extended NPM that was derived from this work now had a general character, and the generative mechanisms and components to which it referred were not exclusive to complex interventions or even healthcare. They referred instead to generic properties of implementation processes and offered an explanation of them without reference to specific social contexts. We therefore presented it as a general, and generalizable, middle-range theory, (Normalization Process Theory, henceforth NPT [1, 31]), that seeks to explain the processes of *implementation*, *embedding*, and *integration* of material practices in formally defined contexts, relates these processes to causal social mechanisms [32], identifies components of those mechanisms, and defines the investments that are required to energize them. The mechanisms of the NPT are described in **Box 4** and its specific constructs in **Box 5**.

### **Road testing Normalization Process Theory**

Just as development of the NPM involved a process of ‘road testing’ to decide whether it was sufficiently plausible and robust to merit formal testing, so did the NPT. We accomplished this using multiple methods. It is important to emphasise that the purpose of this work was not to formally test the theory, but rather to demonstrate that it was *fit* to be tested.

- (i) *Assessing the stability of NPT constructs.* Researchers working in very different contexts and on very different studies (including studies of ehealth implementation and the design and delivery of new food products in the UK, the assessment of clinical decision-making tools at the Mayo Clinic, and the reconfiguration of primary care mental health services in the State of Victoria,

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Australia) worked with the constructs of the NPT to develop analyses of implementation and embedding processes. The criteria for stability were (a) that the generic constructs could be translated into specific contexts without the addition of ad hoc conditions; and (b) that sceptical researchers were able to use them in practice with minimal support. This process was qualitative, but its criterion for success was a simple one. It was that researchers involved in this process would subsequently and independently choose to use the NPT for further work. It met this criterion.

- (ii) *Critical comparison of NPM and NPT constructs.* A key question was whether or not expanding the scope of normalization process analysis to the higher level constructs of the NPT has practical value. In other words we wanted to be clear that there was an advantage to using the NPT. To this end, we coded two sets of data (interview transcripts from a study of ehealth implementation processes, and qualitative data collected in systematic review of ehealth implementation studies) using *both* the NPM and NPT. We sought confidence that NPT covered the ground we claimed for it, and that propositions could be derived from it that could effectively test the data and which would lead to robust explanations of observed phenomena. This process was qualitative, but the criteria for success were also simple. We asked, did the NPT confer an analytic advantage by explaining more of the data? And, could the NPT explain more of the data without forcing it to fit? In practice, we found that it could.

To summarise: ‘road testing’ NPT required that we establish that its constructs actually defined mechanisms, components, and investments, that could all be prospectively revealed by empirical research, and that these could be characterised in a stable way. We then had to demonstrate that these constructs could be operationalized in a way that conferred an analytic advantage. This involved two sceptical groups of researchers (in Melbourne, led by JG; and at the Mayo Clinic, led by VM) approaching NPT’s constructs critically, interrogating them and their definitions in practice, and being sufficiently satisfied with the results of this process to build them into ongoing research projects in which they could then be tested. This process was important because it paralleled the final revisions of the NPT as subsequently accepted for publication.

### ***Relationship between the NPM and NPT***

The formal theory (NPT) does not conflict with the applied model (NPM) from which it was drawn. In fact, it extends it. The constructs of the NPM are central to the formal theory and constitute its collective action component. The NPM is unchanged by this, and researchers could continue to use the NPM in settings where only those factors that promoted or inhibited collective action were at issue. The NPT, however, extended the applied theoretical model to include the ways by which actors make sense of a set of practices, the means by which they participate in them, and the forms of appraisal that they apply.

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## RESULTS

This paper has described the procedures by which Normalization Process Theory was developed. The development of a set of explanatory ideas around normalization has shifted from an initial set of empirical generalizations presented as synthetic propositions or assertions [2], to a robust conceptual model that presented generalizable propositions [3], and finally to a middle range theory that offers a set of mechanism-based explanations for processes of implementation, embedding and integration [1]. This has involved a steady shift away from context dependent statements (see **Box 6**).

The processes of theory development described here have included changes in scope, as well as method. Simply accounting for this is unusual, but is a necessary precondition for research that subjects the NPT to formal and definitive tests. It is important to show that the theory has been derived through processes that have involved the application of relatively robust methods, that these methods have been applied in a properly sceptical way, and that the outcomes of their application have been critically assessed. Despite different streams of writing about theory development in the social sciences—for example, writing around the construction of grounded theory [33-37], and about the development of formal sociological theory [12, 38, 39]—we actually have few factual accounts of the development of theories themselves. When they exist, these often take the form of personal histories [40], or accounts of particular social networks [41]. So, although there are many papers that seek to present some new theory, we can often discover little about where they come from or about the methods by which they were derived. Unless there is already a large body of literature that presents studies that have interrogated or tested a theory in play, we are then stuck with the problem of how to evaluate its relation to the phenomena that it seeks to explain. Such theories often seem to spring fully formed from critiques of the literature or from empirical observations. We have sought to avoid this problem.

## CONCLUSION

If there is not a great deal of literature about theory-building there may be too much about theory builders. Even so, it is important to understand that all such work takes place in the context of what the Polish physician, Ludwig Fleck—writing in the 1920s—called ‘thought collectives’ [42]. Writing about thought collectives, Fleck, along with many later sociologists interested in the creation of technical and scientific theories and worldviews, was concerned about the place and influence of the social and political contexts in which these creations come about. Our aim in this research has been to develop a robust explanatory model that can underpin structured, prospective, studies, which have both practical and policy relevance, and which are genuinely open to interdisciplinary inquiry. Unusually for a theory building process, this has been a highly collaborative one, in which co-investigators in these studies and others have made very important contributions to the development of theoretical explanation. Our view is that

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while this is very interesting and needs to be accounted for, this must be done elsewhere. At this stage it is actually much more important to say *what happened*. The theory itself is described in detail elsewhere [1], and accounts of research that tests the theory, for good or ill, are forthcoming.

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## **CONFLICT OF INTERESTS**

The authors declare that they have no competing interests.

## **CONTRIBUTORS**

Authorship ordered according to the time-point at which contributors joined in the work of theory development described in this paper, and their contributions are attributed on the following basis. The programme of theory building was led by CRM who also drafted this manuscript. Phase 1 included CRM, FM, TF & AMacF; Phase 2 included CRM, FM, TF, CFD, AMacF, ST, TR, BNO, AR, EM, GE, FL; in Phase 3, formal theory development was done by CRM and TF. Other contributions to work in this phase were made by FL, FM, EM, JG, and VM. All of the above have contributed practically and intellectually to the work that led to this paper and have commented and agreed on the manuscript.

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**Figures and tables**

**Box 1: Empirical Generalizations on normalization**

**Box 2: Propositions of the Normalization Process Model**

**Box 3: Division of constructs: Macro to Micro**

**Box 4: General Propositions of Normalization Process Theory**

**Box 5: Specific Propositions of Normalization Process Theory**

**Box 6: The changing scope of the theory**

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**Box 1: Empirical Generalizations on normalization processes [2]**

*P<sub>1</sub> Implementation* of telemedicine services depends on a positive link with a (local or national) policy level sponsor, so that telemedicine is defined as an appropriate means of delivering care, and appropriate infrastructures are developed.

*P<sub>2</sub> Adoption* of telemedicine systems in service depends on successful integration at the level of structural legitimation so that it is supported as, and thus practically incorporated into, health care delivery through the development of organizational structures.

*P<sub>3</sub> Translation* of telemedicine technologies into clinical practice depends on the enrolment of heterogeneous actors into relatively cohesive, co-operative groups, in which functional identities are negotiated and established *a priori* and powers relatively well defined.

*P<sub>4</sub> Stabilization* of telemedicine systems in practice depends on integration at the level of professional knowledge and practice, where clinicians are able to accommodate telemedicine in their clinical activities through the development of new procedures and protocols.

*P<sub>5</sub> The normalisation* of telemedicine as a means of health care delivery (in whatever setting, and at whatever level of healthcare provision) is conditional on  $P_1 + P_2 + P_3 + P_4$ .

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**Box 2: Propositions of the Normalization Process Model [3]**

$P_1$  A complex intervention is disposed to normalization if it confers an interactional advantage in flexibly accomplishing congruence and disposal;

$P_2$  A complex intervention is disposed to normalization if it equals or improves accountability and confidence within networks;

$P_3$  A complex intervention is disposed to normalization if it is calibrated to an agreed skill-set at a recognizable location in the division of labour;

$P_4$  A complex intervention is disposed to normalization if it confers an advantage on an organization in flexibly executing and realizing work.

**Box 3: Division of constructs: Macro to Micro [28]**

<p><b>Domain of work (Macro level)</b> <i>(Defined as generative mechanisms in Normalization Process Theory)</i></p>	<p><b>Everyday practices (Micro level)</b> <i>(Defined as constructs of the Normalization Process Model)</i></p>
<p><b>Coherence:</b> Work that defines and organizes the objects of a practice.</p>	<p>Practices that ensure <b>contextual integration</b> with healthcare systems and services.</p>
<p><b>Cognitive Participation:</b> Work that defines and organizes the enrolment of participants in a practice.</p>	<p>Practices that are defined by their <b>skill-set workability</b> within formal and informal divisions of healthcare labor.</p>
<p><b>Collective Action:</b> Work that defines and organizes the enacting of a practice.</p>	<p>Practices that are defined by their <b>interactional workability</b> within a set of everyday social relations.</p>
<p><b>Reflexive Monitoring:</b> Work that defines and organizes the knowledge upon which appraisal of a practice is founded.</p>	<p>Practices that ensure <b>relational integration</b> of knowledge and practice in a network of actors</p>

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**Box 4: General Propositions of Normalization Process Theory [1]**

*Material practices become routinely embedded in social contexts as the result of people working, individually and collectively, to implement them.*

From this follow specific propositions that assert that define a mechanism (i.e. embedding is dependent on socially patterned implementation work).

*The work of implementation is operationalized through four generative mechanisms (coherence; cognitive participation; collective action; reflexive monitoring).*

From this follow specific propositions that define components of a mechanism (i.e. those factors that shape socially patterned implementation work).

*The production and reproduction of a material practice requires continuous investment by agents in ensembles of action that carry forward in time and space.*

From this follow specific propositions that define actors' investments in a mechanism (i.e. how the mechanism is energized).

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## **Box 5: Specific Propositions of Normalization Process Theory**

### **Coherence**

Routine embedding is dependent on work that defines and organizes a practice as a cognitive and behavioural ensemble.

Embedding work is shaped by factors that promote or inhibit actors' apprehension of a practice as meaningful.

The production and reproduction of coherence in a practice requires that actors collectively invest meaning in it.

### **Cognitive participation**

Routine embedding is dependent on work that defines and organizes the actors implicated in a practice.

Embedding work is shaped by factors that promote or inhibit actors' participation.

The production and reproduction of a practice requires that actors collectively invest commitment in it.

### **Collective action**

Routine embedding is dependent on work that defines and operationalizes a practice.

Embedding work is shaped by factors that promote or inhibit actors' enacting it.

The production and reproduction of a practice requires that actors collectively invest effort in it.

### **Reflexive Monitoring**

Routine embedding is dependent on work that defines and organizes the everyday understanding of a practice.

Embedding work is shaped by factors that promote or inhibit appraisal.

The production and reproduction of a practice requires that actors collectively invest in its understanding.

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**Box 6: The changing scope of the theory**

I. Clinical Practice  
(highly contextualized empirical generalizations)



II. Complex Interventions  
(decontextualized analytic propositions)



III. Material Practices  
(acontextual generic properties)

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