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EDITORIAL

Integrating Care for Children, Young People and Their Families

John Eastwood

Keywords: Integrated care; children; young people; families; sustainable development

That “children are our future” is becoming increasingly evident as science comes to better understand the inter-generational, epi-genetic, and developmental origins of health and disease. The complex nature of child development, family, school and community environments, and the interplay of social, psychological and biological mechanisms, makes the provision of nurturing and protective services across the age ranges difficult. Approaches required during pregnancy, for example, will be very different to those provided for young people in transition to adulthood.

All societies have thus developed institutions and practices to nurture and protect their young through the various stages of development and transition to adulthood. The organisation and coordination of those activities is usually robust and complex. For some children and their families they will require a number of simultaneous complex inputs. It could be argued that the potential complexity of inputs, as a result of the developmental nature of childhood, is not realised at any other stage of the life-course. This is because each stage of child and youth development has its own unique complexity. Those stages might be defined as: pregnancy and childbirth; infancy (0–12 months), early childhood (0–4 years); middle childhood (5–9 year); adolescence (10–19 years), or early adulthood (20–29 years). The age related definitions are usually defined by demographers, legislators, and service planners, and often vary across service sectors, regions and jurisdictions. There are thus often challenges posed to the provision of seamless services across important developmental transition points, such as from childhood to adolescence, or adolescence to early adulthood with increased fragmentation of care occurring.

To function well the systems usually rely on informed participation of parents, caregivers, children and young people themselves. Children and young people, from about age 3, can be informed and have an active participation in the provision of services. Their involvement can be as active participants in clinical consultations, or through

their involvement in planning and direct action to promote health, education and development in their own schools and communities.

The situation may be very different for families, children and young people living with current, or a previous history of adversity. The impact of that psychological trauma on physical and mental health has only recently been understood. The service system, its workforce, and institutions are often yet to adapt to this new knowledge and understanding. Consequently the behaviours of traumatised families, children and young people are not understood and services often fail those in most need of help. It is here that we are beginning to see the positive impact of “trauma informed” integrated health and social care approaches. Such systems require coordinated inputs from maternity services, childcare, schools, primary care, welfare and housing, income support, mental health, police, and hospitals. Population-based system-wide integrated care approaches utilise stratification of risk to ensure proportionate allocation of resources.

The integration of system-wide policies and services has long provided the foundation for promoting and protecting the health, development and wellbeing of children, young people and their families. The United Nations Convention on the Rights of Children and the Sustainable Development Goals (SDGs) provide the global platform to addressing the needs of children young people and families. The challenges are global. Integration of services for families, children and young people is important in low-income countries, countries affected by war, among refugee and migrant populations, and within rich countries as highlighted by the recent Innocenti Report “Building the Future: Children and the Sustainable Development Goals in Rich Countries” [1].

Integration of “whole of society” services for children, young people and their families has long had a role to play in low-income high-mortality countries. For much of the last 100 years health systems, governments and international agencies have worked to reduce maternal, infant and under-five mortality rates. Much of the improvement in mortality rates has been attributed to sanitation, clean water, fertility control, and improved access to primary health care that has included safe birthing practices and

immunisation. In the face of slow gains in the development of community services in low-income countries, the world community signed the Alma Ata Declaration on Primary Health Care in 1978, and called for, among other things, local integration of services, and stronger community and interagency engagement.

Despite this primary health care focus on integration subsequent international “child survival” initiatives during the 1980s were characterised by a vertical and siloed approaches. Calls for stronger integration were met in the mid-1990s by the development by WHO and UNICEF of the Integrated Management of Childhood Illness (IMCI) strategy for implementation in countries with high child mortality rates. The IMCI strategy includes three components: (1) integrated management of ill children in facilities and health centres; (2) health system strengthening, particularly drugs and logistics support; and (3) community IMCI with a focus on promotion of key family and community practices. The IMCI strategy requires a strong partnership between health workers and families, with support from local communities. Community IMCI aims to reach families and communities in the place where they live. Thereby promoting and enabling the participation of parents, caregivers and communities in their own development.

In the current global health context, the United Nations Convention on the Rights of Children (UNCRC) and the Sustainable Development Goals (SDGs), together provide a global platform to addressing the needs of children young people and families through an integrated system response. Building on the SDG goal of achieving universal health coverage, WHO has developed a global strategy and *Framework for people-centered and integrated health services* [2], recommending that countries consciously consider the perspectives of individuals, families, and communities, and respond to their preferences and needs. The framework builds on the foundations of the earlier Alma Ata Declaration of Primary Health Care (and arguably the Ottawa Charter of Health Promotion), and proposes five interdependent strategies for health services to become more integrated and people-centred. They are: (1) empowering and engaging people and communities; (2) strengthening governance and accountability; (3) reorienting the model of care; (4) coordinating services within and across sectors; and (5) creating an enabling environment.

At heart of achieving the Sustainable Development Goals is also the Global Strategy for Women’s, Children’s and Adolescents’ Health (2016–2030) [3]. That strategy “envisions a world in which every woman, child and adolescent realizes their rights to physical and mental health and well-being, has social and economic opportunities, and is able to participate fully in shaping prosperous and sustainable societies”. Building on the “Global Strategy for Women’s, Children’s and Adolescents’ Health (2016–2030)”, a “Nurturing care for early childhood development” framework was recently launched at the 71st World Assembly [4]. That Framework contains five guiding principles: (1) the child’s right to survive and thrive (a Child Rights principal); (2) leave no child behind

(an equity principal); (3) family-centred care; (4) whole-of-government action; and (5) a whole-of-society approach.

Based on an analysis of effective programmes the WHO Framework proposes five action areas “to empower families to provide nurturing care ... [and] create enabling environments, strong monitoring systems and accountability mechanisms.” The five proposed action areas are to: (1) lead and invest; (2) focus on families and their communities; (3) strengthen services; (4) monitor progress; and (5) use data and innovate.

The two WHO frameworks for people-centered and integrated health services and Nurturing Care provide a useful basis to strengthen current international approaches to Integrating Care for Children Young People and their Families. At the recent International Conference on Integrated Care in Utrecht we called for the establishment of an IFIC special interest group (SIG) for “Integrating Care for Children Young People and their Families”. The SIG aims to bring together health, education and social care practitioners and researchers who are interested in aspects of integrated health and social care as it applies to children, young people and their families. As a group we will discuss service, policy and system approaches and collaborate on Integrated Care research and development projects, including grant proposals.

Our first steps will include: building a broad global network; establishing a community website; linking with other global networks, including Child Health Information for All (CHIFA); defining the definitions and scope of Integrated Health and Social Care as it applies to Children, Young People and their Families; preparing and publishing a joined position paper on ‘Integrated Care for Children Young People and their Families; collaborating on shared research projects; developing and promoting appropriate outcome measures and evaluation frameworks; sharing successes and lessons-learned of Integrated Care as it applies to Children, Young People and their Families; and meet during the International Conferences on Integrated Care. There are challenges in evaluating outcomes and the complex interventions required for integration of care, and thus the required methodological approaches will be a key issue for early discussion within the SIG.

Through this global network we believe that we can share knowledge and experience that will contribute to advancing the vision of the *Health for All*. If you are interested in the IFIC Special Interest Group – Integrating Care for Children, Young People, and Their Families, please contact me at john.eastwood@health.nsw.gov.au.

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Competing Interests

The author has no competing interests to declare.

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EDITORIAL

Making a Realist Turn: Applying a Critical Realist Translational Social Epidemiology Methodology to the Design and Evaluation of Complex Integrated Care Interventions

John Eastwood^{*,†,‡,§}

Keywords:

“Building on the SDG goal of achieving universal health coverage, WHO has developed a global strategy and Framework for people-centered and integrated health services. ... The framework proposes five interdependent strategies for health services to become more integrated and people-centred. They are: (1) empowering and engaging people and communities; (2) strengthening governance and accountability; (3) reorienting the model of care; (4) coordinating services within and across sectors; and (5) creating an enabling environment”[1].

The challenge of achieving people-centred integrated health [and social] services requires the scientific study of interventions and improvements that can achieve the above mutually supporting strategies. Both implementation and improvement science have contribution to make here, but we content that a critical realist methodology will enable a deep understanding of “how and why things are”, and “what will work for whom in what circumstances”.

Implementation science concerns itself with scientific enquiry into matters related to implementation of policies, programmes or individual practices. Much of the current focus is on the translation and implementation of “evidence-based” interventions that were shown to have been efficacious in a controlled setting. The goal of improvement science is to determine which improvement strategies work to assure effective and safe patient care. The intent of both implementation and improvement science in health and social care is to understand how and why interventions work with “real people” in the “real” world, such as with *people-centered integrated health [and social] services*.

Health and social care is conducted, however, within complex systems where the various human actors (with agency) interact with existing, and changing, social and organisational arrangements or “structures”. Interventions that seek to change observed phenomenon, such as disease patterns, will be influenced by these existing conditions. Consequently it is not sufficient to simply assess a change in outcomes or to describe the intervention process. It is instead necessary to diagnose the extant conditions, and then to design, apply and evaluate the prescribed interventions in those “real world” conditions. Here, and in the first four papers of this supplement, we will advance that a critical realist research, design and evaluation approach has merit and should be conducted in partnership with those who will be affected.

For physicians, and other health practitioners, the process will be very familiar as it involves the same modes of study and reasoning undertaken in a complex clinical consultation. In drawing this analogy we highlight the importance of: patient history, context, objective findings, theory building, differential diagnosis or best explanation, evidence-based treatment, monitoring, and re-evaluation of assumptions. The monitoring and re-evaluation is necessary because of patient behaviour, influence of external conditions, fallibility of the diagnosis process, and variability in treatment effectiveness.

The above clinical and system analyses both require consideration of history, structure, culture, relationships, and human reasoning (agency). They both also assess the world in terms of biological, psychological, social, and economic domains. In addition to the observed, or empirical, they also both seek to understand and explain the hidden mechanisms using an “inference to the best explanation” form of reasoning. Finally both will most likely accept the possibility of fallibility, and that their reasoning processes are influenced by their own training, experience, values and beliefs. In taking the above approach, clinicians and system practitioners are arguable both using a critical realist philosophy of science, and the related abductive and retroductive forms of reasoning.

The Philosophy of Science, Critical Realism, is “realist” in that it holds that objects in the world, and in particular

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social objects, exist whether the observer or researcher is able to know them or not; and it is “critical” in seeing knowledge of those objects as always fallible because any attempts at describing them needs to take account of the transitive nature of knowledge. Understanding the world in terms of these intransitive and transitive dimensions has proven especially helpful when applied to the study health and social systems. The critical realist approach to considering reality as stratified, for example in to biological, psychological, social, and economic domains, makes it especially useful for the study of social and organisational systems and for the discipline of translational social epidemiology as it might be applied to integrated care. While focusing here on the discipline of social epidemiology, we acknowledge that similar methods may be used for “organisational research”.

Social epidemiology has developed over the last twenty years are sophisticated approach to the study of health and social systems. To date social epidemiology has been dominated by empirical descriptive studies that draw attention, for example, to the impact of service accessibility, acceptability, availability, and cost, on health and social outcomes. We have previously drawn attention to the challenge for social epidemiology to make a turn from its descriptive empirical “humean” roots toward an applied realist translational discipline, thus using its tools to move from explaining health and social phenomenon, toward designing, implementing and evaluating complex health and social interventions. Such a turn calls for a transdisciplinary approach that moves from studying historical and current organisational and social structures and human behaviours, explaining the observed phenomenon through to the explication of theoretical propositions, and finally designing and evaluating interventions that are most likely to be complex in nature [2].

Muntaner [3] argued for the use of a realist methodology that seeks to generate social interventions in partnership with the affected populations. In making this argument Muntaner was challenging social epidemiologists to move from the study of causal mechanisms (i.e. realist causal theory) toward the applied development of implementation and programme theories [4]. We seek to contribute towards this challenge, and describe a realist translational social epidemiology methodology for the translation of empirically ‘data derived’ causal middle-range theories of social mechanisms, into social programmes (with programme theories). Those theoretical propositions can be operationalized and studied in concrete situations using theory driven approaches.

O’Campo and Dunn [5] have recently observed that “if social epidemiology continues in its current path, we are likely to see a continued growth in empirical studies demonstrating the existence of a variety of different health inequalities, with relatively little contribution to studies that characterise and inform solutions to those inequalities”. We contend that the identification of solutions requires that we change approach from identifying associations or regularities in empirical data to the identification of the causal explanatory mechanisms, and consequently the

application of programme interventions that impact on those causal mechanisms.

In response to this challenge we undertook critical realist social epidemiology programme of research that sought to build a “Theory of Neighbourhood, Stress, Depression and the Developmental Origins of Health and Disease (DoHD)” using maternal postnatal depression as a case-study [2, 6]. A Multi-level concurrent triangulated mixed method study was used to build a realist middle-range theory using an *Explanatory Theory Building Method* [2]

We will described in the accompanying four papers a realist translational social epidemiology programme of research that will use the meta-theory of critical realism to concretise and contextualise the previously described critical realist theory of neighbourhood context, stress, depression and the developmental origins of health and disease. We will situate these studies in the socially disadvantaged regions of Sydney where the local child and family inter-agencies are collaborating to design and implement new programme interventions based on our earlier studies of perinatal, child, youth and family outcomes.

In preparing this methodology we transverse several areas of epistemological and methodological controversy including: critical *versus* scientific realism; MCO, CMO and CIMO forms of realist propositions; causal, programme and implementation theory; Theory of Change *versus* Realistic Evaluation; and the methodological place of statistical structural modelling within a critical realist epistemology.

Central to the methodology is the mixed method study of the extant condition including the history. This may not be immediately obvious from this body of work as our study of the base-conditions was published earlier. We argue that this step is essential in all situations.

Much of the current theory driven and realist evaluation literature begins with existing interventions. The first task in those situations is to identify the underlying programme theory. In preparing this programme of work we were faced with the translation of causal theory to programme and implementation theory. We have proposed as a first step in this methodology the formal translation of the middle-range ‘causal’ theory into a middle-range ‘programme theory’ followed by an intervention design process based on Theory of Change approaches.

The work of Denyer and co-authors [7] is helpful here in making explicit the requirement for a design step in the realist evaluation cycle and Keller and colleagues [8] introduce CIMO logic as useful step in the translation process. It is important to acknowledge here the important contribution that shared visions and collective planning will make to the development of successful Theory of Change. Consumer and practitioner input to the design and evaluation of interventions is critical to their success. We will present two sequential papers that describe the application of the methodology to design 1) an integrated care intervention for vulnerable families and 2) the funded integrated care intervention Healthy Homes and Neighbourhoods.

The final manuscript in this series will described out application of critical realist meta-theory to the UK Medical Research Council (MRC) Framework for evaluating complex health interventions. This Framework has four components, namely 1) development, 2) feasibility/piloting, 3) evaluation and 4) implementation. We adapted the Framework to include: critical realist, theory driven, and continuous improvement approaches. The original MRC Framework, as is common in the field of implementation science, focused only on activities and outcomes. The incorporation of a critical realist methodology added a focus on history, context and mechanisms. The final framework used a multilevel approach that used critical realist mixed-method research to examine not only outcomes, but also *what is working for whom and why*.

At the recent International Conference on Integrated Care in Utrecht we called for the establishment of an IFIC special interest group (SIG) for “Realist Research, Design and Evaluation”. The SIG aims to bring together health, education and social care practitioners and researchers who are interested realist research methods for integrated care. As a group we will discuss service, policy and system approaches and collaborate on Integrated Care research and development projects, including grant proposals.

Our first steps will include: establishing a global network of interested parties; define the role of realist research methods within integrated health and social care; develop position paper; develop a framework for the application of realist research methods within the study of integrated service, policy and system approaches for integrated care; collaborate on research and grant proposals; develop and promote appropriate realist research methods; share knowledge, successes, lessons-learned, and current models of care; establish a community website, and meet during the International Conferences on Integrated Care. There are challenges in evaluating outcomes and the complex interventions required for integration of care, and thus the required methodological approaches will be a key issue for early discussion within the SIG.

Competing Interests

[[COMPETING INTEREST STATEMENT TO BE PROVIDED]]

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RESEARCH AND THEORY

A Critical Realist Translational Social Epidemiology Protocol for Concretising and Contextualising a “Theory of Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHaD)”, Sydney Australia

John G. Eastwood^{*,†,‡,§,||}, Lynn A. Kemp^{†,¶}, Pankaj Garg^{||,§§}, Ingrid Tyler^{**††} and Denise E. De Souza^{††}

Background: We will describe here a translational social epidemiology protocol for confirming a critical realist “Theory of Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHaD)”. The approach will include the concretising and contextualising of the above causal theory into programme theories for child and adolescent interventions that aim to break intergenerational cycles of disadvantage and poor life outcomes. In undertaking this work we seek to advance realist translational methodology within the discipline of applied perinatal and paediatric social epidemiology.

Theory and Methods: The research settings are in metropolitan Sydney. The design will be a longitudinal, multi-level, mixed method realist evaluation of applied programme interventions that seek to break the intergeneration cycle of social disadvantage and poor child health and developmental outcomes. The programme of research will consist of three components: 1) **Operationalization** of the theory and designing of programme initiatives for implementation; 2) **Evaluation** of the translated programme and implementation theory using Theory of Change and critical realist evaluation; and 3) **Theory Testing** of realist hypotheses using both intensive and extensive critical realist research methods including realist structural modelling.

Discussion: The proposed programme of research will assist in translating empirical explanatory theory building to theory driven interventions. The research will be situated in socially disadvantaged regions of Sydney where the local child and family inter-agencies will collaborate to design and implement new initiatives that address significant disparities in childhood development and adolescent outcomes attributed to neighbourhood circumstances, family stress and intergenerational cycles of disadvantage and poor mental health.

Keywords: critical realism; evaluation; theory; developmental origins of health and disease; neighbourhood; social epidemiology; translational epidemiology

Introduction

The importance of the early years as a determinant of later chronic disease, mental illness, crime and adverse health and social outcomes, is increasingly being recognised [1, 2]. Exposure to adversity during sensitive periods of development have been implicated as contributing to lasting

changes in brain structure, emotional regulation and neuro-endocrine function through complex nutrition, metabolic and epigenetic mechanisms [3]. The environmental influences are proposed to be hierarchical including intrauterine, family and household life, and external physical and social environments [4, 5]. This life course

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approach is not temporally limited to one generation but has a complex biological and social link across generations that includes a potential role for family households, culture, local neighbourhoods and regional or national influences [6].

The importance of the early years is increasingly being recognised by policy makers across governments in high income countries [7, 8]. The policy response has acknowledged the requirement to intervene across government sectors and civil society utilising both evidence-informed interventions and, integrated structural and process strategies within complex public sector systems. The Australian state of New South Wales implemented an early childhood (0–8 years) and family focused interagency response, called *Families First*, in 1998 [9]. The NSW interagency response attempted to improve health, development and wellbeing outcomes through the implementation of a wide range of multi-faceted elements in health, education, local government and social care sectors. While that initiative included a number of evidence-based interventions [10], Fischer and colleagues noted that it suffered from structural and processes problems [11].

The NSW health sector interventions were informed by the disciplines of social epidemiology [12, 13], early childhood [14] and the extensive research base related to nurse home-visiting [15]. The work of Starfield [16], Lynch and colleagues [17] and Muntaner [18] drew attention to the need to develop a theoretical understanding of the systems at play, and the complex interplay of context, mechanisms and observed outcomes.

In response to this challenge we undertook critical realist programme of research, in South Western Sydney, that sought to build a “Theory of Neighbourhood, Stress, Depression and the Developmental Origins of Health and Disease (DOHD)” using maternal postnatal depression as a case-study [19, 20].

Multi-level mixed method studies were used to build a realist middle-range theory of “Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHD)” [21] using an *Explanatory Theory Building Method* [19] (**Figure 1**). The findings of the Emergent and Construction Phases have been previously reported [22–28].

A conceptual framework of maternal depression, stress and context was described (**Figure 2**).

Muntaner [29] has subsequently argued for the use of a realist methodology that seeks to generate social interventions in partnership with the affected populations. In making this argument Muntaner was challenging social epidemiologists to move from the study of causal mechanisms (i.e. realist causal theory) toward the applied development of implementation and programme theories [30]. We seek to contribute towards this challenge, and describe a realist translational social epidemiology methodology for the translation of empirically ‘data derived’ causal middle-range theories of social mechanisms, into social programmes (with programme theories). Those theoretical propositions can be operationalised and studied in concrete situations using theory driven approaches. The programme of research will be undertaken in metropolitan Sydney, Australia.

The *Confirmatory Phase* of research seeks to confirm, further develop and test the middle-range theories constructed. We will describe here a methodology for the *Confirmatory Phase* with an emphasis on the concretising and contextualising of theory in applied programme interventions that seek to:

1. Break the intergeneration cycle of social disadvantage and poor child health and developmental outcomes.
2. Move from explaining the underlying social mechanisms to generating social interventions.

Theory and Methods

Critical Realism

A number of authors have elaborated the application of critical realism to both theory development and theory testing [31–38]. The purpose here is to introduce the central tenants of the critical realist meta-theory relevant to the methodology described below.

We contend as articulated by Bhaskar [39], that critical realism is an appropriate meta-theory for both the generation of causal explanations in social epidemiology and their translation to social interventions as well as confirmation of such causal theories and the evaluation of their

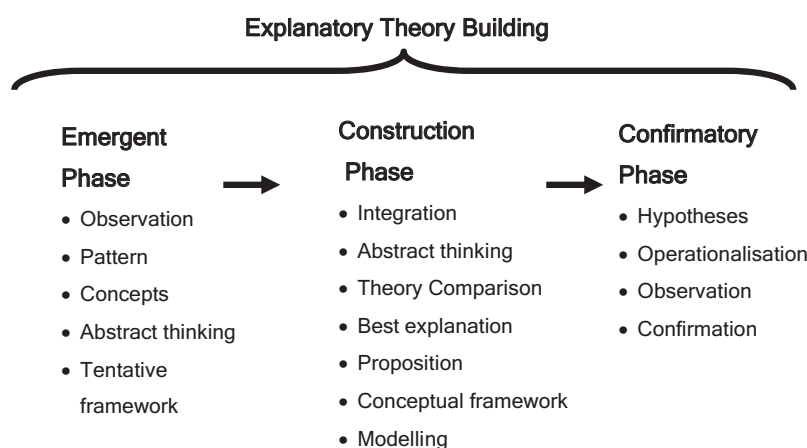


Figure 1: Phases of Explanatory Theory Building.

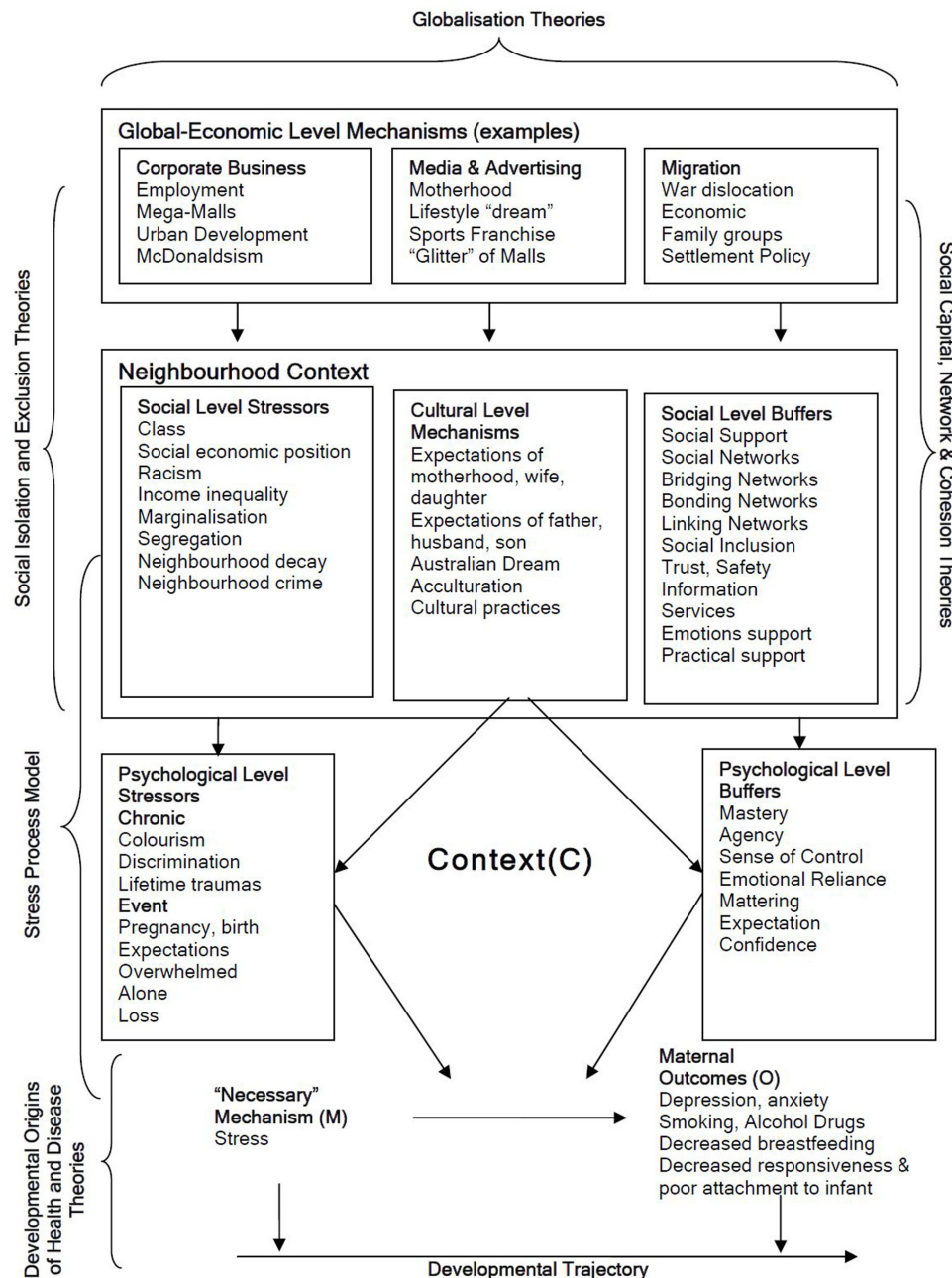


Figure 2: Conceptual Framework of Maternal Depression, Stress, and Context.

concretisation and contextualisation of social interventions. We have previously noted that:

“Critical realists perceive that reality consists of unobservable elements beyond our empirical realm that are still reachable by scientific inquiry. In arguing that social reality can be known, even though the social world is unpredictable and complex, critical realism offers a conception of the real that is fundamentally different from the empirical realism of the natural sciences. A central aspect of critical realism ontology is the distinction between three ontological domains: the empirical, the actual, and the real. The empirical domain comprises our experiences of what actually happens (i.e., experiences), and the actual is made of things that happened independently of whether or not we observed them (i.e., events). The

last ontological domain, the real, is the deepest level of reality and is constituted by mechanisms with ‘generative power’.

A second critical realist ontological dimension is that reality is stratified. Reality is assumed to consist of hierarchically ordered levels, where a lower level creates the conditions for a higher level. The higher level is not, however, determined by the lower level and has its own ‘generative mechanisms’. The existence of these level-specific generative mechanisms is what constitutes or defines a level. The different levels, or strata, have been variably described as including physical, chemical, biological, psychological, psychosocial, behavioral, social, cultural, and economic components. Each stratum is separate and distinct and may interact with the layer above or below to produce new mechanisms, objects, and events” [27]

The ability of mechanisms to combine to create something new is called *emergence*. It is the existence of these level-specific mechanisms that will define an ontological level or layer within what Bhaskar and Danermark call a laminated system [40]. Layder [41] illustrated this layering of reality in his Research Map [41] (**Figure 3**). *Emergence* and the hierarchy of levels are both central tenants of the confirmatory and evaluation methodology described in this protocol. Important also is the analysis of pre-existing historical structural elements.

The idea that an event will not always follow from a causal mechanism, in an open system, is called a *tendency*, where the contextual conditions for the mechanisms to operate may not exist. *Context*, thus, determines how a mechanism is empirically manifest [42–44]. The concept of mechanisms is central to realist ontology. Such mechanisms can exist beneath the empirical surface in the *real* domain and, therefore, are not directly observable. Thus, for realists explanation depends on identifying causal, or

program, mechanism and how they work, and discovering if they have been activated and under what conditions” [45, p 14].

Realist causal propositions are expressed in terms of mechanisms (M), context (C), and outcomes (O). The MCO propositions in our previously reported theory [20] are in the form proposed by Danermark and colleagues [35] (**Figure 4a**). For evaluation studies, Pawson and Tilley [34] propose a CMO configuration as in **Figure 4b**.

In realist programme evaluation terminology the mechanism (M) is an intervention mechanism (IM), and not a causal mechanism. Denyer and colleagues [46] draw attention to the importance of specifying the intervention separate from the mechanism and proposed the use of a CIMO-logic (Context, Intervention Mechanism, Outcome). Thus a CIMO is a hypothesis that the programme theory produces a change (O) because of the action of an intervention (I) on an underlying mechanism (M) operating in particular contexts (C) **Table 1**.

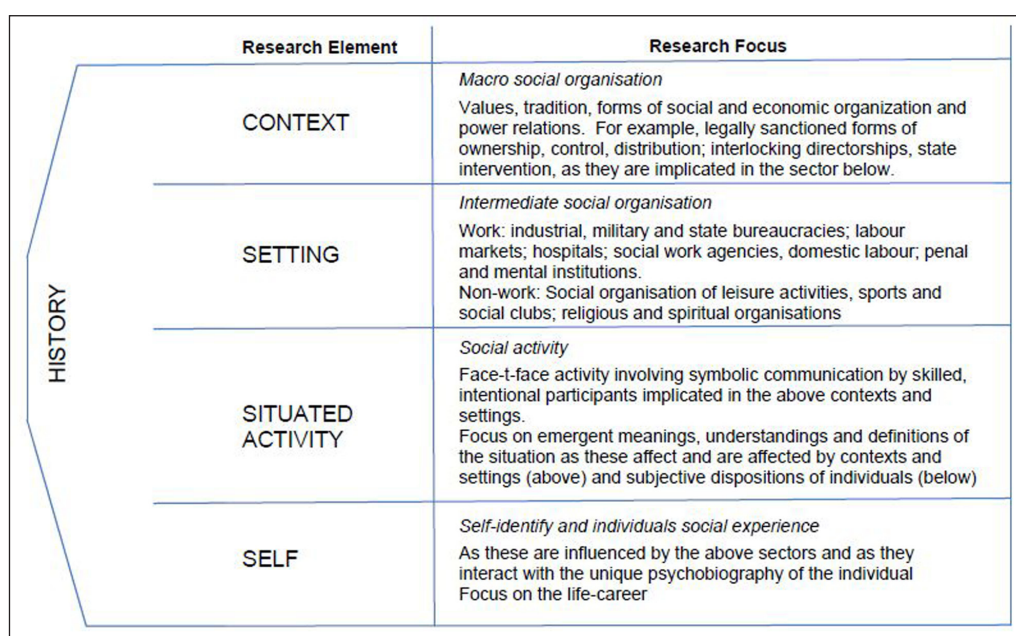


Figure 3: Research Map [41, p 72].

Table 1: CIMO-logic – the Components of Design Propositions [46].

Component	Explanation
Context (C)	The surrounding (external and internal environment) factors and the nature of the human actors that influence behavioural change. They include features such as age, experience, competency, organizational politics and power, the nature of the technical system, organizational stability, uncertainty and system interdependencies. Interventions are always embedded in a social system and, as noted by Pawson and Tilley (1997), will be affected by at least four contextual layers: the individual, the interpersonal relationships, institutional setting and the wider infrastructural system.
Interventions (I)	The interventions managers have at their disposal to influence behaviour. For example, leadership style, planning and control systems, training, performance management. It is important to note that it is necessary to examine not just the nature of the intervention but also how it is implemented. Furthermore, interventions carry with them hypotheses, which may or may not be shared. For example, ‘financial incentives will lead to higher worker motivation’.
Mechanisms (M)	The mechanism that in a certain context is triggered by the intervention. For instance, empowerment offers employees the means to contribute to some activity beyond their normal tasks or outside their normal sphere of interest, which then prompts participation and responsibility, offering the potential of long-term benefits to them and/or to their organization.
Outcome (O)	The outcome of the intervention in its various aspects, such as performance improvement, cost reduction or low error rates.

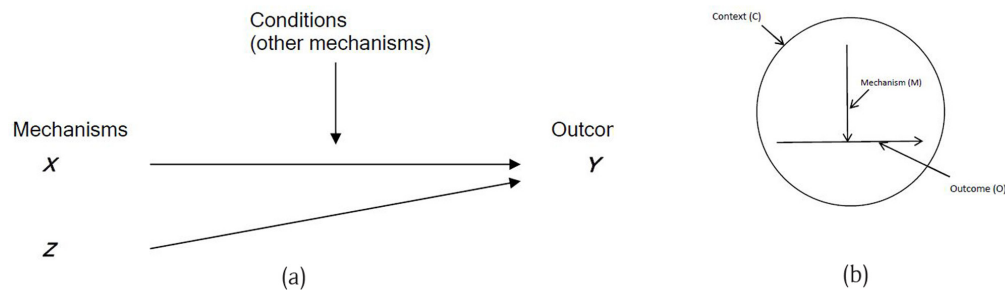


Figure 4: CMO Propositions: **(a)** Danermark et al [35]; **(b)** Pawson and Tilley [34].

We will use CIMO here to differentiate the programme hypotheses from causal hypotheses as used by other realist methodologists [35, 36].

Explanatory Theory – Confirmatory Phase

We propose to use in this programme of research the *Confirmatory Phase* of *Explanatory Theory Building Method*, introduced above (**Figure 1**) [19]. *Explanatory Theory Building Method* uses induction, abduction, retroduction and deduction as the central forms of reasoning moving from description of the concrete, to the abstract, and back to the concrete [35, p 109–111].

In this approach the researcher begins with descriptive and exploratory examination of the phenomena, events and situations intended for study. This is followed by an analytical process that involves identification of components, abduction and retroduction, comparison of theories and abstractions, and concretisation studies of the theorised mechanisms in different (contextual) situations. The *Confirmatory Phase* builds on the Concretisation and Contextualisation stage described by Danermark and colleagues [35]. Realist hypotheses are developed from the theoretical propositions, operationalised, and studied in concrete situations. We summarise below two approaches as elaborated by: Sayer [36, 45] and Pawson and Tilley [34].

Realist research methods proposed by Sayer [36, 45] can be used for both the development and confirmation of realist causal hypotheses. Sayer [36] emphasised the importance of different methods of data collection and analysis. He proposed four types of research: intensive or concrete (empirical and theoretical analysis); generalisation (empirical), abstract (theoretical) and synthesis (interdisciplinary analysis). Sayer [45] further outlines two different kinds of research design relevant to the programme of research described here. The “intensive research design” is used in research where we wish to obtain in-depth knowledge of a specific phenomenon for the purpose of causal explanation. “Intensive research design” mainly applies to qualitative methods. “Extensive research” typically uses more quantitative methods that seek to identify regularities and patterns. The “extensive” study typically identifies regularities and has limited explanatory power (i.e. of how and why).

A realist approach to evaluation of programme mechanisms was advanced by Pawson and Tilley [34]. The approach assumes that whenever a programme is implemented it is testing an existing programme theory consisting of realist programme hypotheses (CMOs). This is assumed to be the case even if the theory was not

made explicit. Consequently one of the tasks of a realist programme evaluation is to make the programme theory explicit by developing clear realist programme hypotheses about how, and for whom, programs might ‘work’. Subsequently the evaluation of those programme hypotheses can be done. The Realist [Programme] Evaluation approach usually starts with a programme that has been designed. The process of designing a programme intervention using realist causal theory is not well explicated.

Theory driven design and evaluation

Theory-driven approaches to the design and evaluation of complex community initiatives are informed by the Aspen Institutes Theories of Change framework [47, 48], and the Realist Evaluation approach. Astbury and Leeuw [49] observe that the methodology for constructing or reconstructing programme theory varies significantly. They observe that programme theory can be developed before a programme is implemented or after it has been running for some time. More often Theories of Change and realist evaluation start from the basis of an existing programme [34, 48, 50]. Consequently the translation of explanatory causal theory to design theory and programme theory is not well described. The use of realist synthesis goes some way to addressing this translation process but is only useful if there have been previous programmes of a similar nature.

For the purposes of this protocol we have drawn on the work of Keller and colleagues [51] who present a realist design-evaluation framework that combines design theory and realist evaluation. In their model programme, kernel [core] theories are used to develop the design propositions which are evaluated by realist evaluation, resulting in further refinement of the programme or kernel theories.

The Theory Driven Evaluation (TDE) approach is concerned with the evaluation of a programmes impact. As with realist evaluation the first task is to make the programme implementation theory explicate. Renger and colleagues [52] note that this is not required for other approaches to process evaluation but it is necessary when undertaking a theory driven approach as in our research protocol. They further argue that the “*articulation of [the] implementation theory is essential for a meaningful process evaluation to be completed*”.

Blamey and Mackenzie [30] examine these matters further in their comparison of Theories of Change and Realist Evaluation. Citing Weiss [53, p 58] they define “implementation theory” as “*what is required to translate objectives into ongoing service delivery and programme operation*”

and “programme theory” as ‘*the responses of the people to programme activities*’. Blamey and Mackenzie [30] also observe that *programme theory* is referred to as ‘middle-range’ theory by Pawson and Tilley [34].

Blamey and Mackenzie [30], propose that Theories of Change be used as a means of explicating *implementation theory* for the purpose of programme planning, improvement and the development of robust monitoring systems at a macro programme level; while realist evaluation approaches be used to examine micro level aspects of the most promising *programme theories*.

Thus for the programme of research described here we will: 1) develop programme theory based on the causal theory and then apply that to deliberately designed interventions [46, 51]; and 2) confirm the causal theory using methods proposed by Sayer [36, p 243].

Research Design

The research settings will be in metropolitan Sydney. The research design will be a longitudinal, multi-level, mixed method realist evaluation of applied programme interventions that seek to break the intergeneration cycle of social disadvantage and poor child health and developmental outcomes. The programme interventions are likely to include: targeted home visiting and parenting services, place-based community and school initiatives, and whole of system “collective impact” and integrated care approaches.

In summary, programme theory will be developed using the causal theory developed as part of the *Emergent and Construction Phases* previously described, together with other relevant published theories, meta-syntheses and realist synthesis. The programme design propositions and hypotheses will be expressed, in realist terms, as context-intervention-mechanisms and outcome (CIMO) conjectures, which will thus render the full constituents of the programme theory. Intervention initiatives will be designed and implemented by interagency collaborations that draw from the local government, health, education and social care sectors. In doing so, we aim to move from explaining underlying social mechanisms to generate social interventions in partnership with the affected populations [29].

The intervention design process will use a theory driven approach utilizing Theory of Change (ToC) and related logic models [54]. Implementation theory will be developed, and the initial programme theory adapted for use in real world circumstances (i.e. concrete contexts). Using a longitudinal realist evaluation approach hypotheses will be refined through ongoing data collection and analysis.

The research programme will consist of three phases:

1. **Operationalisation** of the theory and design of programme initiatives for implementation
2. **Evaluation** of the translated programme and implementation theory using critical realist evaluation
3. **Theory Testing** of realist hypotheses using both intensive and extensive critical realist research methods.

Ethics approval to conduct this research has been sought and obtained from the Sydney and South Western Sydney Local Health District Ethics Committees.

Operationalisation

Stage 1: Causal and Programme Theory

The purpose of the Operationalisation Phase is to move from abstract *causal* theories to concrete applied *implementation* and *programme* theory. In the operationalisation phase we will: expand the layered domains used for realist causal MCO hypotheses, and the number of MCO hypotheses; identify relevant programme theory from other relevant published theories, meta-syntheses and realist synthesis; map context-intervention-mechanism-outcome links, and generate suitable MCO and CIMO hypotheses for empirical testing and programme evaluation respectively.

Expand Layered Domains

We will expand the layered domains used for the MCO hypotheses and revisit the psychological and social layers, with a particular focus on mechanisms identified in the Stress Process Model [55]. The Stress Process Model is concerned with explaining ways in which social structures influence mental health with a focus on the connection between disadvantaged social status and psychopathology. The *Construction* phase of our previous explanatory theory building limited the development of realist causal hypotheses to the psychological-social layers related to maternal stress and depression [20]. Abductive and retroductive analysis undertaken during theory development, and theory construction also identified potential MCO configurations in other domains which will be relevant to programme development and evaluation. Those domains included, for example: access to services and information; strengthening of social capital, social cohesion and social inclusion; the role of local government, housing and social care services, media and corporate business (**Figure 2**). The intention will be to make explicit the *laminated system* in the manner as described by Bhaskar and Danermark [40]. The output of this analysis will be a table of causal MCO configurations for which appropriate intervention and programme theory will be sought.

Relevant Programme Theory

Using the expanded layered domains and causal MCO configurations as a framework, we will identify prospective intervention and programme theory from relevant published theories, meta-syntheses and realist synthesis. The methods used will include: a literature review of published theories, meta-syntheses and realist syntheses using search terms derived from the expanded domains and causal MCO configurations; and Delphi studies in areas judged to be critical to subsequent programme design. The table of causal MCO configurations will be modified to include: causal mechanisms (M_c), prospective programme interventions (I), and programme mechanisms (M_p) thus, developing design propositions following the context-intervention-mechanism-outcome (CIMO)

logic (Denyer, [46]. The identified programme theory will be tested as part of the design and implementation of suitable initiatives.

Stage 2: Initiative Design

In the second stage of the Operationalisation Phase we will undertake: collaborative design of suitable initiatives using theory driven approaches; define the implementation theory; apply programme theory to the logic model; and outline an evaluation approach.

Collaborative Design

New South Wales (NSW), Australia introduced the *Families First* initiative in July 1999. The aim of *Families First* was to support families and communities to care for children. The initiative draws on existing services and resources, and had a strong focus on coordinating network of services. The initiative was later renamed *Families NSW* and had a foundation of local interagency groups supported by programme management groups (PMGs) at District level. Collaborative planning will be used to develop suitable initiatives that can be used to operationalise the programme theory.

The nature of those initiatives cannot be determined with certainty, but are likely to involve interagency approaches to prevention and early intervention that identifies and supports those children and families most likely to require further assistance. The interventions currently being considered include: perinatal coordination, home visiting, place-based initiatives, parenting programmes, and school transition initiatives.

Collaborative design will determine the approach which will be taken, but the use of theory-based evaluation methodology will be preferred. Sector training in Results Based Accountability [56], a data driven decision making process, has provided a foundation for collaborative theory informed planning of programmes. Consequently, it is envisaged that Theory of Change and Logic Models will be able to be constructed.

The difficulties of developing Theory of Change through collective and collaborative processes are, however, well recognised [57]. Mackenzie and Blamey outline a set of steps that if followed will result in identifying an initiatives Theory of Change. "Those steps are as follows:

1. Identification of the long-term outcomes that the initiative seeks to achieve
2. Identification of the interim outcomes and contextual features that will be required to meet these longer-term outcomes
3. Specification of the activities that will be put into place and the contextual requirements to realise those interim outcomes
4. An explicit recognition of the resources that will be required to turn those goals into reality" [57].

Using a critical realist approach, the collective design will also require a historical analysis to be undertaken to elaborate the pre-existing structures and mechanisms contributing to the observed maternal, child and family outcomes [58].

Define Implementation and Programme Theory

The theory-driven approaches will help in making clear the inputs, activities and outcomes expected. This is usually visually expressed as Logic Models or results chains. A key feature of theory driven evaluation is the need to know what components of the intervention contribute to achieving its impact. It is necessary to understand the theory that underpins the mechanisms and programme mediators. Intervention theory applies to the 'nuts and bolts' of the intervention (i.e. activities, target groups, settings) and programme theory relates to the 'responses of the people to programme activities' (i.e. psychological mechanisms) [59]. We will review the logic models or results chains developed as part of the collaborative Theory of Change process and add appropriate programme theory mechanisms. This process may require additional literature reviews to those undertaken in Stage 1 of the Operationalisation Phase.

Evaluation

The evaluation phase will be longitudinal with ongoing data collection, and refinement and augmentation of the theory and hypotheses developed in the Operationalisation Phase by drawing on emerging empirical evidence. We will collect qualitative and quantitative data on the context, mechanisms, intervention implementation, receipt, reach, acceptability and normalization (i.e. likely sustainability). A focus of the data collection will be on how intervention mechanisms interact with causal mechanisms and pre-existing context to generate changes in outcomes (also referred to as demi-regularities).

Stage One: Contextualisation of Case Studies

Danermark [35, p 168] observed that in order to explain we must study how mechanisms manifest themselves in concrete contexts. The initiatives to be evaluated will be complex with likely multiple contexts and layers as described by Layder [41, p 73] above. We anticipate that it will be necessary to focus the evaluation on one level and stage of the logic model (i.e. case-studies). The description of the various contexts will require a full historical and current perspective of the layered context. At the individual client level the contextualization will entail a full personal and family history similar to that undertaken in a comprehensive social interview. Where the evaluation is focusing on a situated activity or setting, the documentation is likely to require an exploration for historical pre-existing features of the setting that may themselves be mechanisms with generative power. Given the nature of the causal theories being investigated we intend to, where possible, focus on: 1) maternal and family contexts; 2) practitioner contexts; 3) place-based settings; and 4) interagency contexts. The pre-existing vertical relationships in the laminated system will also be examined.

Stage Two: Concretisation and Instrumentation

The implication of the above is that the evaluation will examine causal and programme interventions in different concrete situations. The hypotheses developed in the Operationalisation Phase will be used to develop data

collection tools and approaches for those 'concrete situations'. It is likely that modifications will be required for interview, focus group, and quantitative instruments to ensure acceptability, appropriateness and validity. For the purposes of our programmes based in Sydney, modifications will be required for data collection from Aboriginal and Torres Strait Islander populations, and those of ethnic and culturally diverse backgrounds. It will also be necessary to modify our data collection approach where domestic violence and severe psychological or physical trauma has been experienced. Given the emergent longitudinal nature of the research we anticipate that the data collection tools will require modification after each analytical cycle.

Stage Three: Realist Evaluation Data Collection

A mixed method approach will be undertaken to data collection. We will take an integrated approach to methods, data collection and analysis [60–62]. Yin [60] argues that without such integration "*different methods may sit in parallel, potentially leading to multiple studies, and not the desired 'mixing' of methods implicit in mixed methods research*". Yin proposes that integration should occur in relation to: research questions, units of analysis, samples for study, instrumentation and data collection methods, and analytic strategies. The research design will strive to achieve the standards of integration proposed by Yin with integration occurring through use of common research questions, study design, units of analysis, samples for study and analytic strategies during both emergent and construction phases. We will assess the quality of the mixed method approach using frameworks proposed by Teddlie and Tashakkori [63, p 300] and Onwuegbuzie and Johnson [64].

Qualitative Data

The nature of the interventions to be evaluated has not yet been determined. The qualitative methods will be tailored to each intervention, and specifically to the programme theories and contexts being studied. Realist methodology is permissive of the data collection methods used and can draw from the traditions of phenomenology, grounded theory, and interpretivism. Qualitative data will be collected, for example, from:

- a) Documentary sources
- b) Case-notes completed by the intervention deliverers (i.e. community workers, facilitators, educators, clinical staff)
- c) Researcher direct observations
- d) Interviews with intervention deliverers, interagency partners and consumers of the intervention
- e) In-depth case studies involving participant observation, focus groups and interviews in a selection of settings
- f) Delphi surveys
- g) Social network analysis studies.

The qualitative research will capture the participants own understandings and meanings of the intervention and what is working, for whom, in what context. The research may suggest hypotheses about the complex mechanisms by which the intervention may, or may not work. It can be

anticipated that mechanisms will be identified that were under-theorised in Phase 1. As observed by Jamal and colleagues [65], the "*qualitative data may provide important insight into contexts and unintended pathways that can then be tested via quantitative mediation and moderation analyses*". As argued elsewhere, we will therefore, use an emergent theory approach to refine the theory and CIMO hypotheses prior to the quantitative model testing.

Quantitative Data

Quantitative data will be used for both programme and implementation evaluation. Those two purposes are quite distinct with the instruments chosen for programme evaluation being derived from both the causal (MCO) and programme (CIMO) hypotheses developed in Operationalisation Phase, and subsequently modified during the implementation evaluation. Given the longitudinal emergent nature of the evaluation it is anticipated that some quantitative measurements will be added or altered during the course of the evaluations. We consider that addition or amendment of quantitative measures enables more valid testing of the middle range theories to be undertaken in the Theory Testing Phase.

Stage Four: Intervention Evaluation Data Collection

It is anticipated that a number of the interventions will be subject to implementation process reporting requirements determined by external funders. For the process evaluation to be meaningful it is important to articulate the implementation theory as discussed above. While implementation theory pertains to programme activities, the intention is to capture not only the steps of an activity but also the essence of how the activities affect the mechanisms of change identified in the programme theory [52]. The intervention data collection will, therefore, focus on capturing two types of data: 1) whether the programmes were delivered as intended; and 2) the process of implementation and how the activities influenced the hypothesised programme interventions (CIMO).

Stage Five: Refining the Intervention

As stated above, the evaluation phase will be an emergent longitudinal study with ongoing data collection, and refinement and augmentation of the theory and hypotheses developed in Operationalisation Phase by drawing on emerging empirical evidence. Such an approach is widely used in realist evaluation and is in keeping with the realist evaluation cycle [34, p 85, 66, p 29]. The evaluation of programme theory will be used to inform the intervention design, and may in certain circumstances lead to modification of the actual implementation.

Evaluation of the Intervention process, implementation theory and programme theory will almost certainly result in modification to the actual intervention design and implementation. This "*action*" approach to intervention implementation is widely accepted within health and social care, where trial and learning methodology are increasingly used. The use of PDSA (plan, do, study, act) cycles [67] within NSW health sector evaluations is common and will be used where appropriate or required by funding agencies.

Theory Testing and Triangulation

The theory testing phase will test hypotheses using quantitative and qualitative studies, and further refine causal, programme and implementation theory. The empirical analysis will include 1) intensive (qualitative) studies, case studies and extensive (quantitative) modelling to test causal CMO hypotheses arising from the *Operationalisation Phase*; and 2) quantitative modelling of CMO hypotheses derived from the *Evaluation Phase*. Triangulation of the empirical, process and outcomes studies will be used to refine the causal, programme and implementation theories.

Realist evaluation of causal hypotheses

Separate from the evaluation studies described above we intend to undertake mixed method intensive studies, case studies and quantitative modelling to test and refine causal hypotheses arising from the Operationalisation Phase. The intensive studies will use interviews, focus groups and concept mapping methods. The critical realist case studies will use the approaches described by Sayer [36], Maxwell [68], Easton [69] and Yin [70]. The extensive (quantitative) modelling studies will use multi-level, spatial and structural equation modelling methods. The purpose of the empirical studies will be to 1) replicate and extend our earlier studies, and 2) study the causal theories in settings quite separate from the programme evaluation(s).

Realist modelling of programme mechanisms

We will use the structural modelling approach recently described by Jamal and colleagues [65]. In keeping with earlier realist studies by Kazi [66] the programme evaluations will use previously validated psychometric instruments as measures of hypothesised mechanisms and outcomes. For example measures of child development and behaviour, self-reported health, self-efficacy, depression, isolation, and health literacy.

Discussion

We have described here a realist translational social epidemiology protocol for a programme of research that will use the meta-theory of critical realism to concretise and contextualise previously described critical realist theory of neighbourhood context, stress, depression and the developmental origins of health and disease. We will situate these studies in the socially disadvantaged regions of Sydney where the local child and family inter-agencies are collaborating to design and implement new programme interventions based on our earlier studies of perinatal, child, youth and family outcomes [71–74]. Of particular concern to our communities are the significant disparities in early childhood development and adolescent outcomes that might be attributed to neighbourhood circumstances, family stress and intergenerational cycles of disadvantage and poor mental health.

The application of realist methodologies to social epidemiology and population health interventions is relatively new. O'Campo and Dunn [38] have recently observed that "*if social epidemiology continues in its current path, we are likely to see a continued growth in empirical studies*

demonstrating the existence of a variety of different health inequalities, with relatively little contribution to studies that characterise and inform solutions to those inequalities". We contend that the identification of solutions requires that we change approach from identifying associations or regularities in empirical data to the identification of the causal explanatory mechanisms, and consequently the application of programme interventions that impact on those causal mechanisms. In undertaking a programme of explanatory theory building, we have responded to the call to contribute to social theory for informing translational social epidemiology. The planned realist multi-level mixed method studies will identify individual level explanatory mechanisms, and operationalised postulated social and cultural structures. The abductive and retroductive theory building constructed middle-range theories, which we propose will be formally tested through theory driven evaluation, realist programme evaluation, case studies and statistical modelling.

In preparing this methodology we transverse several areas of epistemological and methodological controversy including: critical *versus* scientific realism; MCO, CMO and CMO forms of realist propositions; causal, programme and implementation theory; Theory of Change *versus* realist evaluation; and the methodological place of statistical structural modelling within a critical realist epistemology. Based on the philosophical analysis advanced by Maxwell [68] we find no justification to reject the application of critical realist ontological and epistemological meta-theory to programme evaluation. We also contend that the realist evaluation and realist synthesis methods advanced by Pawson and Tilley [33, 34] are consistent with Maxwell's position. Pratschke [75] refutes, successfully in our opinion, the scepticism of some critical realist philosophers toward statistical methods. His views are supported by Olsen [76–79], Mingers [80] and others. Latent variables and structural equation modelling (SEM) also has a strong realist foundation within the Latent Variable Theory [81]. Consequently SEM will have important utility in testing our critical realist causal and programme theories.

Conclusion

Central to this methodology is the development of programme theory. Much of the theory driven and realist evaluation literature begins with existing interventions. The first task in those situations is to identify the underlying programme theory. In preparing this programme of work we were faced with the translation of causal theory to programme and implementation theory. We have proposed as a first step in this methodology the formal translation of the middle-range 'causal' theory into a middle-range 'programme theory' followed by an intervention design process based on Theory of Change approaches. The work of Denyer and co-authors [46] is helpful here in making explicit the requirement for a design step in the realist evaluation cycle and Keller and colleagues [51] introduce CMO logic as useful step in the translation process.

It is important to acknowledge here the important contribution that shared visions and collective planning will make to the development of successful Theory of Change. Consumer and practitioner input to the design

and evaluation of interventions is critical to their success. A challenge to critical realist practice is the presentation of complex abstract constructs in simple language. Particularly important will be the communication of causal hypotheses. As previously observed, the strength of the critical realist approach will be the extent to which this paradigm can support the epistemological, ontological, axiological, methodological and rhetorical positions of applied translational social epidemiological research in concrete contexts.

Reviewers

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Competing Interests

The authors have no competing interests to declare.

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RESEARCH AND THEORY

Designing Initiatives for Vulnerable Families: From Theory to Design in Sydney, Australia

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Introduction: Intergenerational cycles of poverty, violence and crime, poor education and employment opportunities, psychopathology, and poor lifestyle and health behaviours require innovative models of health care delivery to break them. We describe a program of research informed service development targeting vulnerable families in inner metropolitan Sydney, Australia that is designed to build and confirm a theory of “Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHaD)”. We describe the development of an intervention design and business case that drew on earlier realist causal and program theoretical work.

Methods: Realist causal and program theory were used to inform the collaborative design of initiatives for vulnerable families. The collaborative design process included: identification of desirable and undesirable outcomes and contextual factors, consultation forums, interagency planning, and development of a service proposal.

Results: The design elements included: perinatal coordination, sustained home visiting, integrated service model development, two place-based hubs, health promotion and strengthened research and analysis capability.

Conclusions: We demonstrate here the design of interventions for vulnerable families in Sydney utilising translational research from previous realist causal and program theory building to operational service design. We have identified the importance of our earlier analysis of underlying causal mechanisms and related programme mechanisms for identifying the elements for the full intervention design. The application of theory added rigour to the design of the integrated care initiatives. In applying the theory to the local situation the analysis took into account: the role of the local agencies; evidence of program effectiveness; determinants and outcomes for local children and their families; the current deployment of service resources; and insights from front-line staff and interagency partners.

Keywords: critical realism; evaluation; theory; developmental origins of health and disease; neighbourhood; social epidemiology; translation; collaborative design; child; families

Introduction

Inequities in the health and wellbeing of Australian children and families who live in disadvantaged communities are growing [1–3], despite a range of government initiatives designed to alleviate the impact of disadvantage and social exclusion [4].

Key to this is the issue of how we break the intergenerational cycles of poverty, violence and crime, poor education and employment opportunities, psychopathology, and poor lifestyle and health behaviours (including: unhealthy nutrition and physical activity, tobacco and substance use, interpersonal violence, early and unprotected

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sexual activity) [5]. Longitudinal cohort studies, some for three generations, have identified intergenerational transmission of psychopathology, poor parenting practices and family dysfunction that contribute poor health outcomes throughout the life course (including: suicide, teen age pregnancy, obesity, depression, tobacco smoking, diabetes and cardiovascular disease) [6]. Implicated as predictors of intergenerational transmission are: child abuse, harsh parenting practices and socio-economic disadvantage [7–9].

Increased understanding of the complex and inter-related issues that contribute to poor outcomes for vulnerable disadvantaged families have prompted concern from researchers and service providers about the often fragmented and inefficient service response, one that is not specific to local community needs [10]. This has prompted an increased policy commitment to community-led, multi-disciplinary, cross-sector integrated service delivery [11, 12]. There is limited research on how to design or build an evidence-informed integrated response to complex social problems.

Critical realism offers an approach to empirically inform theory building and collaborative design of social interventions [13, 14]. As a philosophy of science, it contends that there is a natural and social reality that exists independently of empirical observation and human thought. Those unobservable structures and mechanisms, under certain conditions, cause the observed events, and can be discovered and understood. Thus critical realism requires an understanding of the social situation or context, and requires the investigation of underlying mechanisms (causes) behind the observed events. In the study and practice of integrated care, the critical realist approach requires the inclusion of an analysis of pre-existing

structures and mechanisms that may be contributing to the observed maternal, child and family outcomes [15], followed by an analysis of how an intervention may work to produce the desired change in observed outcomes.

It is well recognised that the early years play an important role in the genesis of later adult health and disease. Current theory construction is focused on how various genetic and environmental mechanisms interact to influence life course outcomes. The environments implicated are: intrauterine, the maternal-infant dyad, family and household life, and external social and physical environments" [16]. Our critical realist theory building analysis [17] used the theoretical frames of: Stress Process; Social Isolation; Social Exclusion; Social Services; Social Capital, Acculturation Theory and Global-economic level mechanisms to explain our observed inequities in maternal outcomes. In our previously reported analysis stress was identified as the underlying "necessary mechanism" that has the tendency to cause several of the observed outcomes including depression, anxiety, and health harming behaviours (**Figure 1**) [17]. Our ecological and multilevel empirical studies supported the theoretical proposition that neighbourhood adversity causes maternal psychological distress and depression within the context of social buffers including social networks, social cohesion and social services [18]. The theoretical causal propositions from that body of work were subsequently used to generate programme theory which was used in the design study reported here [19, 20].

Metropolitan Sydney has been described as being "a city divided" [21–25] with social disadvantage clustered in the southern and western districts. Local perinatal and paediatric social epidemiology studies have further identified

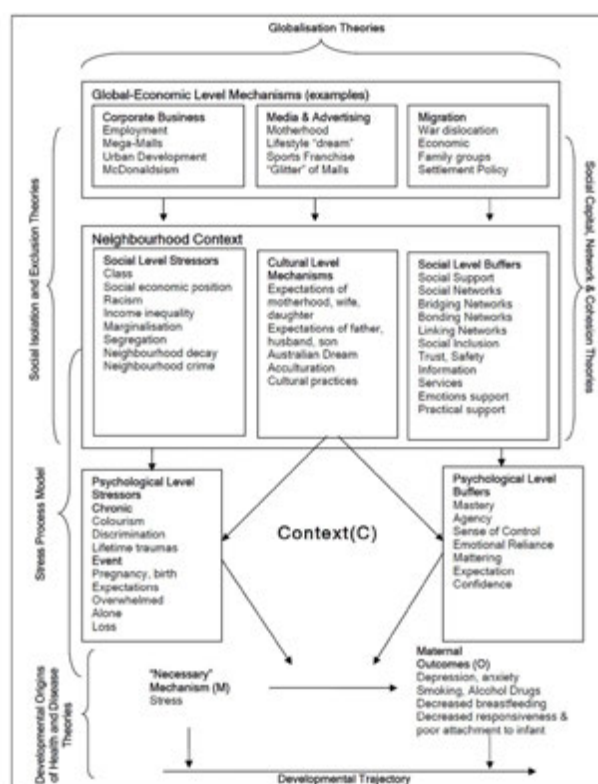


Figure 1: Conceptual Framework of Maternal Depression, Stress and Context [17].

socially deprived neighbourhoods and populations with poor perinatal, child and family outcomes [26–29]. Within Sydney Local Health District (SLHD), located in Central and Inner West Sydney, the clustering of social disadvantage and poor perinatal, child and family outcomes is evident in the Cities of Canterbury, Marrickville and Sydney [28].

The SLHD was established in 2011 and the following year the District commenced a program of collaborative interagency work to address the needs of children, young people and their families. An early focus of that work was on the special needs of families living with increased psychological and social stress. This paper will describe the development of an intervention design and business case that drew on our earlier realist causal and program theoretical work and is part of a program of research and program development that seeks to build and confirm a theory of “Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHaD)”. The work was undertaken from 2010 to 2014.

Theory and Methods

The overall research design is a longitudinal, multilevel, critical realist evaluation of applied programme interventions. The longitudinal dimension involves repeated measures of the output, produced after implementing the program, at different points in the course of the program running (time 1, time 2, time 3). The multilevel aspect incorporates the investigation of different levels of mechanisms operating at the psychological level of self, the level of situated activity, and the levels of intermediate and macro level services. The intervention initiatives, responding to the conceptual framework (Figure 1), were designed and implemented by interagency and community collaborations. In doing this we aimed to move

from “explaining underlying social mechanisms to generate social interventions in partnership with the affected populations” [30].

The main research programme comprised of four phases (Figure 2). The methodology used for the four phases was reported separately [19]. In summary the four phases are: 1) operationalization of programme theory and intervention development and planning; 2) evaluation of the interventions; 3) theory testing studies; and 4) dissemination of the findings. In this paper we report on one of the collaborative design projects undertaken in Phase 1: Operationalization.

Critical realism and programme design

Critical realist philosophy of science seeks to discover the underlying mechanisms (M) that cause an empirically observed event or outcome (O). The idea that an event will not always follow from a causal mechanism, in an open system, is called a *tendency*, where the contextual conditions for the mechanisms to operate may not exist. Thus it is important that the nature of the pre-existing conditions be examined. Critical realism also holds that reality is stratified so that each level has its own mechanisms and it is the existence of these level-specific mechanisms that constitute or define a level. The ability of mechanisms to combine to create something new is called *emergence*. Layder [31] illustrated this layering of reality in his Research Map (Figure 3). In this study we will use the following modification of the levels proposed by Layder [31], namely, Self, Situated Activity, Setting -Intermediate Level Social Organisation and Context – Macro Level Social Organisation. Mechanisms, emergence, a hierarchy of levels, and pre-existing historical conditions are all central to the critical realist design process described here.

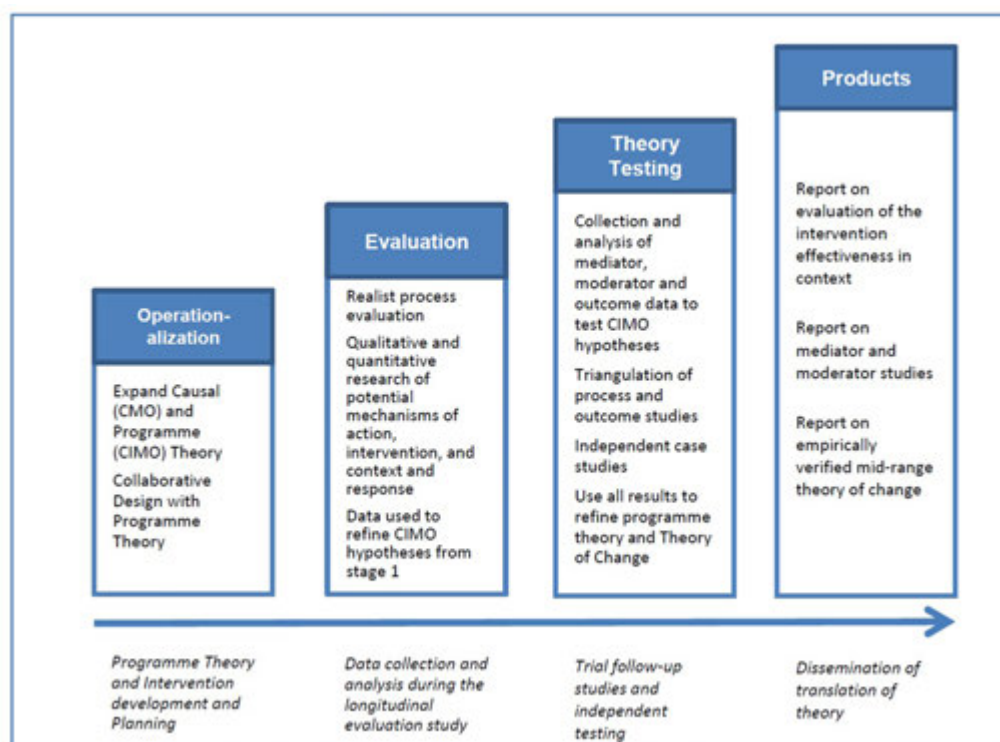


Figure 2: Summary of Research Programme.

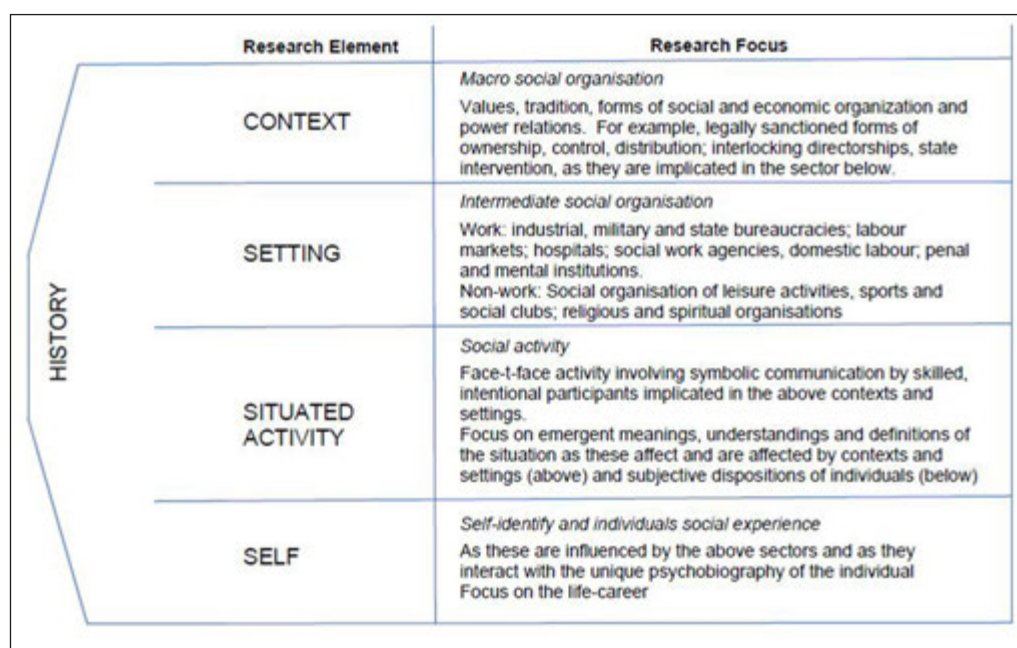


Figure 3: Research Map [31].

Realist causal propositions are expressed in terms of mechanisms (M), context (C), and outcomes (O). The MCO propositions in our previously reported theory [17] are in the MCO form proposed by Danermark and colleagues [32]. For evaluation studies, Pawson and Tilley [33] have proposed a CMO configuration. In realist programme evaluation terminology the mechanism (M) is an intervention mechanism (IM), and not a causal mechanism. Denyer and colleagues [34] draw attention to the importance of specifying the intervention separate from the mechanism and proposed the use of a CIMO-logic (Context, Intervention Mechanism, Outcome). Thus a CIMO is a hypothesis that the programme theory produces a change (O) because of the action of an intervention (I) on an underlying mechanism (M) operating in particular contexts (C). We will use the CIMO logic in this study and will apply it to the development of the Theory of Change (ToC) logic model (**Figure 6**).

Realist programme evaluation usually starts with a programme that has been already designed. The approach assumes that whenever a programme is implemented it is testing an existing programme theory consisting of realist programme hypotheses (CMOs). The process of designing a programme intervention using realist causal and programme theory is not well explicated. For the purposes of this study we have drawn on the work of Keller and colleagues [35] who present a realist design-evaluation framework that combines design theory and realist evaluation.

Collaborative Design

The collaborative design of the integrated care initiative involved: 1) planning forums; 2) shared outcome planning; 3) collaborative interagency planning; and 4) preparation of a fully funded business plan, Theory of Change and logic model.

1. The development of a Theory of Change using collective and collaborative processes can be difficult. We used the set of steps proposed by Mackenzie and Blamey [36]
2. Identification of the long-term outcomes that the initiative seeks to achieve
3. Identification of the interim outcomes and contextual features that will be required to meet these longer-term outcomes
4. Specification of the activities that will be put into place and the contextual requirements to realize these interim outcomes
5. An explicit recognition of the resources that will be required to turn these goals into reality.

The design analysis integrated our earlier causal and programme theoretical work, and the 2013 collaborative design for vulnerable families. Consequently the critical realist theoretical framework guiding the collaborative effort incorporated 4 elements:

1. a historical analysis of the context to theorise the pre-existing social structures and mechanisms [15]
2. proposed design elements of an intervention, stemming from inputs from forums, interviews and collaborations during 2013 and 2014
3. the development of a programme theory hypothesising the pre-existing situational conditions and causal mechanisms, and specifying how the proposed intervention would trigger desired psychological, motivational and behavioural responses to bring about change [14]
4. the construction of Theory of Change (ToC) logic model explicating a proposed implementation theory [14].

Ethics

The planning undertaken here did not include human subjects. Ethical approval was not sought. The indicator reports used secondary data and did not require ethics approval. The earlier cited mixed method multilevel studies had ethics approval from the University of New South Wales.

Results and Design

Historical Analysis of the Context

At the level of service providers, the New South Wales (NSW) Government, Australia, introduced an interagency initiative for families in 1999. This was known as *Families First*. The aim of *Families First* was to support families and communities to care for children. The initiative drew on existing services and resources, and had a strong focus on coordinating a network of services. The initiative was later renamed *Families NSW* and has a foundation of local interagency groups supported by programme management groups (PMGs) at District levels. The Inner West Collaborative Programme Management Group (CPMG) plays a significant role in the planning of services for families within SLHD and is a pre-existing social structure with mechanisms that the present design initiative will aim to reconfigure.

At the service to consumers level, in 2009, an epidemiology report of child and family indicators was published that included information on the health and wellbeing of children and families living in both south western and inner west regions of Sydney [27]. In preparation for the

design work described here that report was updated in 2013 for Sydney LHD [28]. Secondary analysis from the child and family indicator data-sets was made available for participants of the Vulnerable Children's Forum and the Supporting Children and Families Forum. That analysis focused in detail on data available for each of the LGAs in SLHD, and was supplemented by a SLHD population needs analysis, and concurrent reviews of perinatal coordination and Infant of Substance Abusing Mothers (ISAM) Pathways [37].

The updated Child and Family Health Indicator Report: Inner West Sydney 2013 [28] and results from Vulnerable Children's Forum 2013 highlighted the challenges faced by service consumers in the Inner West Sydney District context and the service gaps that service providers needed to take into account, respectively. Findings from the recently completed study of "Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHD)" [17] which elaborated realist causal and program theory were also included. That study was undertaken in the neighbouring South Western Sydney LGAs of Bankstown, Fairfield, Liverpool and Campbelltown. Those information sources, in combination, provided information and supported theories about the presenting contextual conditions [C] as shown in **Figure 4** below. The analysis of contextual conditions uses a modification of the four levels proposed by Layder [31].

As earlier mentioned, two consultation forums were held. While the Vulnerable Children's Forum highlighted service gaps in the context of interest, the Supporting

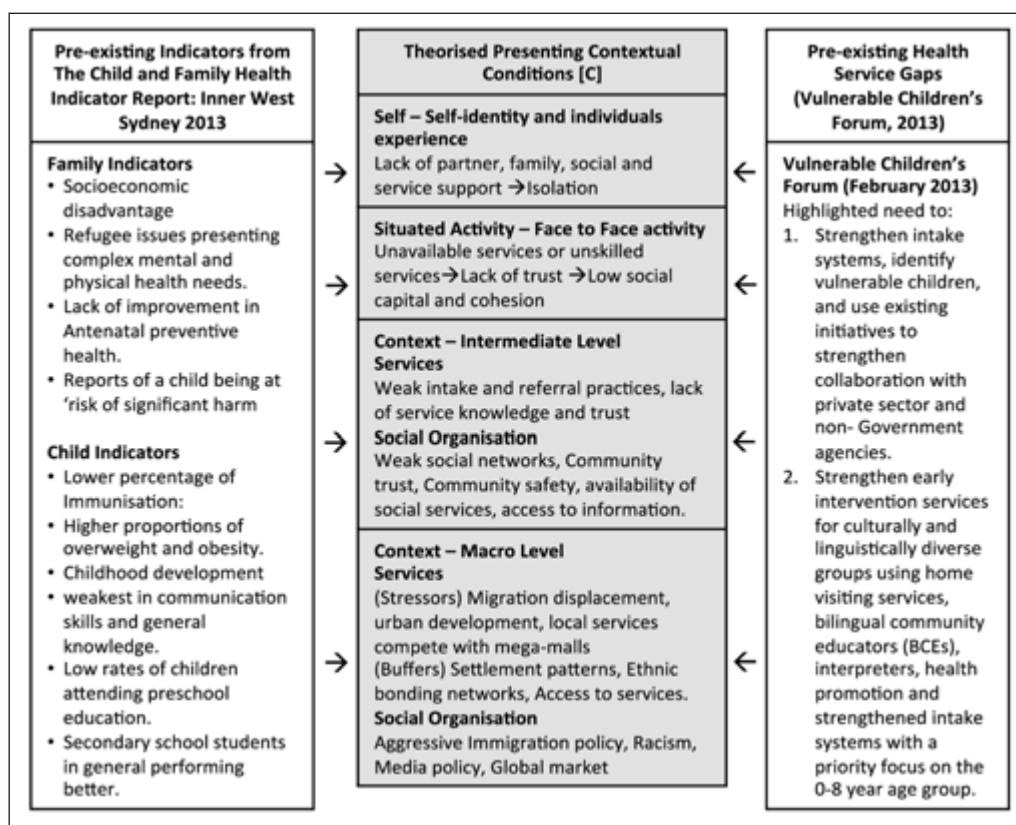


Figure 4: Theorised Contextual conditions.

Children and Families Forum 2014, contributed to the collaborative design by identifying the desirable service provisions. The planning framework included assessment of: 1) the role of the health sector and SLHD, 2) scientific and economic evidence of program effectiveness; 3) determinants and outcomes of SLHD child health and development; 4) current deployment of SLHD resources; 5) current system performance; and 6) insights from front-line staff and interagency partners. A summary of the outcomes of the 2014 forum is shown below (**Figure 5**).

Design Elements

In response to the contextual analyses and consultation forums, a design initiative was formulated which formed the proposed intervention [1].

Three scientifically supported solutions were identified as possible solutions to disrupt the intergenerational cycles of disadvantage observed in SLHD:

1. Sustained Nurse Home Visiting services for vulnerable mothers and their infants until 2 years using a tiered approach [38, 39]
2. Intensive “wrap around” counselling models for “high risk” mothers experiencing interpersonal violence, and with complex mental health and substance use problems [40]

3. Preschool and school-based centre and home visiting interventions to reduce conduct disorder, bullying, depression, and alcohol use [40].

Two Programme Logic supported solutions were also identified to support sector wide delivery:

1. Actively managed integration of services and care-coordination (rather than case management) of interventions for high risk infants and their mothers
2. Community-wide and place-based inter-sectoral initiatives that address the social determinants of child and family health [39].

The design elements were developed for inclusion in: 1) a Vulnerable Family Business Case, and 2) Child and Family Health Planning Priorities (**Table 1**).

Programme Theory

The design elements arising from the collaborative design were informed by sound theoretical propositions regarding the underlying programme mechanisms. The programme theory concerns itself with specifying the potential psychological, motivational and behavioural outcomes produced by interventions at each level or layer.

Supporting Children and Families Forum - 2014

A Supporting Children and Families Forum was held in Burwood, Sydney, on 26th February 2014. Participants were from non-Government agencies (55%), State and Commonwealth Government, (28%), local government (6%) and community agencies (7%). The consultation forum identified the following key themes:

Coordinated Services

- A coordinated service is a network of people sharing responsibility and information respectfully to support families
- The overall outcomes that was wanted was a collaboration of organisation that can identify alternative referral pathways to meet the needs of families
- The strategies and actions that were identified to achieve that outcomes included:
 - working together on projects collaboratively within a child and family interagency
 - removing barriers to the connection of child and family to youth activities
 - ensuring standardised data and the sharing of intelligence and resources
 - creating more informal networking opportunities between services to engage more effectively
- The challenges identified included losing focus on the child and family due to a culture of being too busy and the need of good examples of what a coordinated service looks like

Connected Community

- A connected community is a sense of belonging where everyone is valued and celebrates diversity, showing respect and compassion to each other
- The overall outcome wanted was to build partnerships between services to help build better connections with services for families
- The strategies and actions needed included:
 - Increased outreach to where families and young people gather such as schools, shopping centres and places of worship
 - Creation of more mothers groups for new families
 - Providing better intersection between all interagency
 - Ensuring connection across age groups between youth, child, family and elders
- The challenge identified was lack of funding flexibility and the sharing of knowledge in a consistent way.

Sector Development

- Sector development was defined as increasing the skills and capacity of the community
- The outcome wanted was greater collaboration and communication between the child and family and youth sectors and working with families holistically
- The strategies and action identified included:
 - Further service scoping
 - Implementation of professional practice models for front line staff
 - Cultural competency for staff and leaders to engage more Aboriginal and Torres Strait Islander and CALD communities
 - Keeping families at the centre of our practice, involving clients in providing feedback to professionals on what works and what doesn't
- The challenge identified including acknowledging the constraints, pressures and expectations and then identifying what can actually be achieved.

In summing up the forum the facilitators identified a sector-wide weakness in community engagement. They challenged the participating agencies to identify strategies and action to better connect with the community.

Figure 5: Summary of Consultation Forum.

Table 1: Design Elements.

Design Component	Business Case	Child and Family Health Planning Priorities
Sustained Home Visiting (SHV)	<ul style="list-style-type: none"> • Antenatal screening and risk stratification • Perinatal pathways and coordination • Sustained home visiting commencing before birth • Second tier allied health and medical services, pathways and coordination • Universal maternal, child and family services with proportionate support according to need 	<ul style="list-style-type: none"> • Review and strengthen perinatal coordination • Strengthen Aboriginal SHV (Yana Muru) • New SNV in Canterbury LGA focusing on CALD families • Enhance SHV in Sydney LGA focusing on Redfern and Waterloo suburbs • Strengthen Tier 2 support services including access pathways
Family and Community Integrated Service Development (FCISD)	<ul style="list-style-type: none"> • Integrated service models including wrap-around and family group conference model • Targeted parenting programmes • Domestic violence intervention • High risk infant tracking models • “Hub” and “place-based” community building and service coordination • Universal family and community capacity building (health and wellbeing promotion) 	<ul style="list-style-type: none"> • Interagency collaborative planning • Development of interagency models of care for “high need” schools and early childhood centres • Commence neighbourhood “hub” development in Redfern social housing estate • Enhanced collaborative interagency parenting communication strategy (phone app and web development)
Infrastructure Support (IS)	<ul style="list-style-type: none"> • Child and family public health (epidemiology, programming, research and evaluation) • System change strategies • Service capacity building • Project Management and leadership 	<ul style="list-style-type: none"> • Child and family epidemiology • Evidence-informed programming • Evaluation of perinatal referral pathways • Study of universal well child care system • Web-based health pathway development • Development of well child care and psychological trauma workforce training packages • Leadership and technical support to interagency planning groups

Note: SHV – Sustained Home Visiting; FCISD – Family and Community Integrated Service Development; IS – Infrastructure Support.

The programme theory in **Table 2** below is expressed in realist terms as context-intervention-mechanism and outcome (CIMO) conjectures. The first 2 columns in **Table 1** below highlight the pre-existing Contextual Elements [C] and the prevailing causal mechanisms therein [C_M]. The third to fifth columns highlight the proposed intervention [I], the intervention programme mechanisms [M_p] and the anticipated outcomes [O] resulting, in response to the intervention. The categorised rows indicate how proposed elements of the intervention will work in configuration with each level of the context identified (Self, Situated Activity, Intermediate Level and Macro Level) using the levels or layers proposed by Layder [31] (**Figure 3**).

Theory of Change (ToC)

The ToC Logic Model (**Figure 6**) outlines the hypothesised links between the underlying programme mechanisms (programme theory), the intervention activities (implementation theory), and how they are anticipated to work in synergy to bring about desired outcomes [14].

The ToC Logic model was constructed following steps recommended by Mackenzie and Blamey [41]. Those steps are:

1. Identification of the long-term outcomes that the initiative seeks to achieve
2. Identification of the interim outcomes and contextual features that will be required to meet these longer-term outcomes

3. Specification of the activities that will be put into place and the contextual requirements to realize these interim outcomes
4. An explicit recognition of the resources that will be required to turn these goals into reality [41].

Discussion

We have used critical realist meta-theory to assist in the translation of previously reported empirical explanatory theory building to theory driven interventions. In so doing we have aimed to move from identifying and explaining the underlying social and psychological causal mechanisms, toward generating evidence-informed social interventions in partnership with the affected populations.

We demonstrate the design of interventions for vulnerable families in Sydney utilising translational research from previous realist causal and program theory building to operational service design. For example, previously developed propositions about the underlying mechanisms that cause maternal stress (i.e. loneliness and lack of trust) were used to develop propositions regarding programme mechanisms (i.e. trusting relationships) and design elements (i.e. sustained home visiting) that might buffer this effect.

Local quantitative and qualitative studies were used together with consultation forums and collaborative design approaches. Central to the development of the collaborative design reported here was the infrastructure

Table 2: CIMO Propositions.

Theorised Contextual Conditions (Fig. 2) [C]	Present contextual mechanisms activated [C _m]	Proposed Intervention Design Elements (Table 1) [I]	Postulated Intervention Programme Mechanisms (Table 1) [M _p]	Postulated psychological, motivational and behavioural Outcomes [O]
Self – Self-identity and individuals experience				
Lack of partner and family support, Distrust of services, Limited treatment access	Stress mechanism activated causing anxiety and depression	Friendship and family support, Professional support, Medication, Treatment	Activate mediating mechanisms of family, peer and professional support to strengthen and build trusting relationships with peers, family and clinicians through SHV and FCISD Design Components.	Decreased depression and anxiety
Lifetime trauma, Loss, Being alone, Isolation	Stress mechanism activated arising from mismatched expectations, and loneliness	Family and peer support, Home visiting, Telephone support		Increased perceived support
Situated Activity – Face to Face activity				
Services unavailable or poor access, Services not trusted, Services not skilled	Absence of trusted professional support mechanism	“wrap around” services, Family Conferences, Workforce training	Activate services mechanisms that are client, peer and neighbourhood focused, and trauma and evidence informed through FCISD and IS Design Components.	Improved perceived access to skilled and trusted services
Community distrust, Low social capital and cohesion, crime, unemployment	Absence of trusted neighbourhood and community support mechanism	“wrap around” services, Family Conferences, Public health, Social work services		Improved perceived support from neighbours and community
Intermediate Level social and service organisation				
Unhelpful intake and referral practices, Lack of service, knowledge and trust	Absence of specialist service support mechanism for front-line professionals	Strengthened pathways and design Collocation of services	Activate mechanisms related to trust and confidence with service network, increased local social capital, community trust and community safety	Improved perceived access to services that are “wrapped” around front-line workers
Weak social networks, community trust, community safety, available social services, access to information	Social level stress mechanisms relating to class, position, racism, segregation, crime and neighbourhood decay are activated tending to increase psychological stress	Population and community level interventions in neighbourhoods and communities	Activate mechanisms relating to improved coordination and access to services and information through FCISD and IS Design Components.	Decrease in psychological stress of individuals and families
Macro Level social and service organisation				
Migration, Mega-malls pull service activity away from neighbourhoods, Urban development	Activation of social level stress mechanisms tend to hinder the activation of social level buffer mechanisms	Population and community level interventions in neighbourhoods and communities	Activate mechanisms related to increased social level activities in deprived neighbourhoods.	Increase in perceived social level buffers
Immigration policy, Racism, Media policy, Global market, Settlement patterns, Ethnic bonding networks, Access to services	Migrant related social level mechanisms including acculturation, cultural practices and integration tend to decrease social level stress	Ethnic and cultural specific community and population level interventions	Activate mechanisms related to increased migrant related social activities among ethnic populations through FCISD and IS Design Components.	Increase in perceived migrant social level buffers

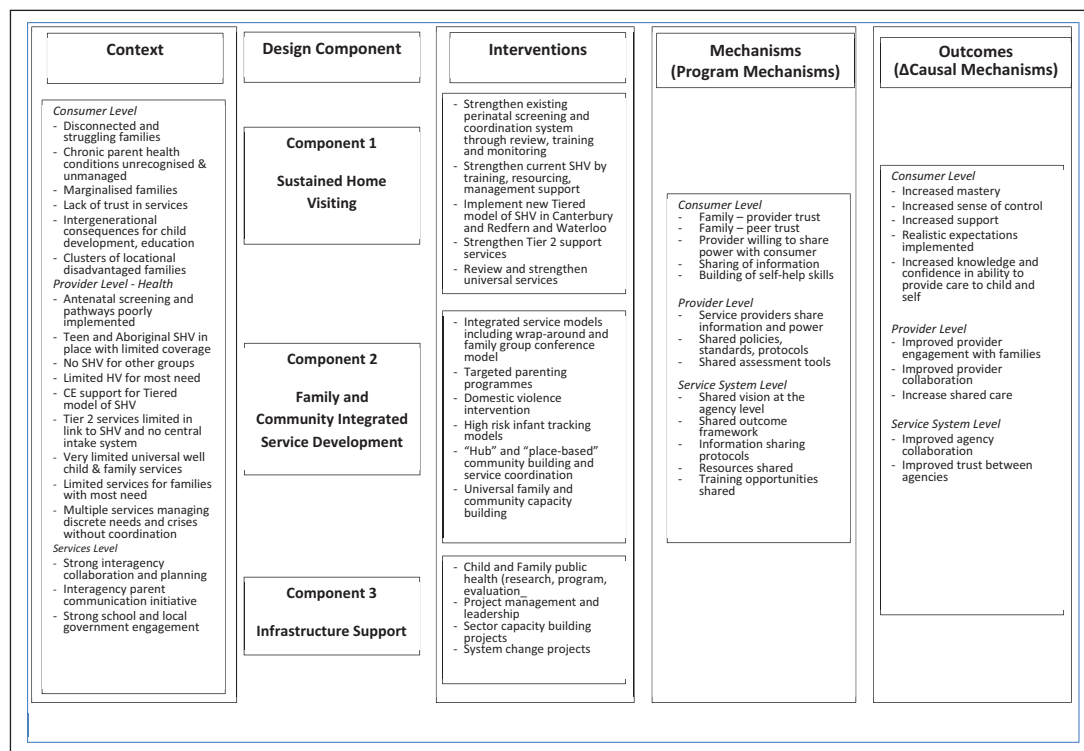


Figure 6: ToC Logic Model.

provided by a network of interagency collaborative groups established as part of the Families NSW initiative. Both consultative forums contributed to the development of shared long-term and interim outcomes and the identification of activities that if put in place could realise those outcomes. Resources necessary to initiate those activities were identified and included into a health sector business plan.

Limitations

The critical realist approach requires the inclusion of an analysis of pre-existing structures and mechanisms that may be contributing to the observed maternal, child and family outcomes [15]. The use of research findings from neighbouring South Western Sydney introduced a weakness into the design process which was only partly offset by the local forum, stakeholder interviews and the perinatal drug health study [37]. A further limitation of the analysis and design elements was the strong health sector focus despite the collective approach to planning. This weakness was partly attributable to significant restructuring of the NSW Departments of Education, and Family and Community Services, which was undertaken during the planning process.

The programme theory used to inform the intervention remains tentative and will require testing during the implementation phase. The design propositions developed followed the context-intervention-mechanism-outcome (CIMO) logic proposed by Denyer [34]. We are not aware of this approaching being applied previously to the translation of causal theory to programme theory. We propose that the robustness of this approach be assessed as part of the evaluation of the design implementation.

Conclusion

In undertaking this study we identified the importance of our earlier analysis of underlying causal mechanisms and related programme mechanisms for identifying the elements for the full intervention design. The application of theory added rigour to the design of the integrated care initiatives. In applying the theory to the local situation the analysis took into account: the role of the local agencies; evidence of program effectiveness; determinants and outcomes for local children and their families; the current deployment of service resources; and insights from front-line staff and interagency partners.

Abbreviations

CPMG: Collaborative Programme Management Group, DOHaD: Developmental Origins of Health and Disease, CMO: Context, Mechanism, Outcome, CIMO: Context, Intervention, Mechanism, Outcome, ISAM: Infant of Substance Using Mother, NSW: New South Wales, SHV: Sustained Home Visiting, SLHD: Sydney Local Health District, ToC: Theory of Change, TDE: Theory Driven Evaluation.

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Competing Interests

The authors have no competing interests to declare.

Author Contributions

JE conceptualised the design and drafted the manuscript. LK provided critical and technical contribution. All authors read and approved the manuscript.

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RESEARCH AND THEORY

Designing an Integrated Care Initiative for Vulnerable Families: Operationalisation of Realist Causal and Programme Theory, Sydney Australia

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Introduction: In July 2015 Sydney Local Health District (SLHD) implemented an integrated care initiative for vulnerable families in the inner West region of Sydney, Australia. The initiative was designed as a cross-agency care coordination network that would ensure that vulnerable families: had their complex health and social needs met; kept themselves and their children safe; and were connected to society. We will describe the development of the design that drew on earlier realist causal and program theoretical work.

Methods: Realist causal and program theory were used to inform the collaborative design of an initiative for vulnerable families. The collaborative design process included: identification of desirable and undesirable outcomes and contextual factors, stakeholder consultation, interagency planning, and development of a service proposal.

Results: The design elements included: identification of vulnerable family cohorts; care coordination; evidence-informed intervention(s); General Practice engagement and support; family health improvement; placed-based neighbourhood initiatives; interagency system change and collaborative planning; monitoring of individual and family outcomes; and evaluation.

Conclusions: The design study described advances toward the implementation of a whole-of-government integrated health and social care initiative. The initiative was designed as a cross-agency care coordination network that would ensure that vulnerable families: had their complex health and social needs met; kept themselves and their children safe; and were connected to society. In so doing we aim to break intergenerational cycles of poverty, violence and crime, poor education and employment opportunities, psychopathology, and poor lifestyle and health behaviours, through strengthening family resilience, improving access to services, and addressing the social determinants of health and wellbeing.

Keywords: Child and Family; Integrated Care; Critical Realism; Design

Introduction

We have previously argued that chronic and complex health conditions have their origins in early childhood and that there is complex intergenerational transmission of their antecedents through probable genetic, epigenetic, behavioural, psychological and psychosocial mechanisms [1]. Our empirical and theory building studies had identified the important causal role that maternal stress

plays in those developmental origins of health and disease. In addition, the critical realist theory proposed that social policy and social services play an important role in buffering the adverse effects of isolation and lost expectations [1]. The findings from those earlier studies have been used to inform the development of interagency integrated care initiatives for children and their families described here.

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In July 2015 Sydney Local Health District (SLHD) implemented an integrated care initiative for vulnerable families in the inner west region of Sydney, Australia. The initiative was designed as a cross-agency care coordination network that would ensure that vulnerable families: had their complex health and social needs met; kept themselves and their children safe; and were connected to society. The initiative was part of a New South Wales (NSW) Government Integrated Care Strategy initiated in March 2014 and drew on the analysis of an earlier design study for vulnerable families undertaken from 2010 to 2014 [2].

The objective of the NSW Integrated Care Strategy was to transform the delivery of care to improve health [and wellbeing] outcomes for patients and reduce costs deriving from inappropriate and fragmented care, across hospital and primary care services. The NSW Government indicated that this objective was to be achieved by: a) focusing on organising care to meet the needs of targeted patients and their carers, rather than organising services around provider structures; b) designing better connected models of health [and social] care to leverage available service providers to meet the needs of our smaller rural communities; c) improving the flow of information between hospitals, specialists, community and primary care providers; d) developing new ways of working across State government agencies and with Commonwealth funded programs to deliver better outcomes for identified communities; and e) providing greater access to out-of-hospital community-based care, to ensure patients receive care in the right place for them.

The NSW Government's stated policy intent was to respond to the challenges of an ageing population and increased numbers of people living with chronic and complex conditions by investing in new, innovative models of integrated care, transforming the health system to routinely deliver person-centered, seamless, efficient and effective care, particularly for people with complex, long term conditions. Funding was made available, through a competitive grant process, for health districts to develop innovative integrated care projects. The functional elements of the NSW Health Integrated Care Strategy are shown at **Table 1**.

The Inner West Sydney District collaborated to design initiatives for vulnerable families in 2013. A critical realist design method was applied and included programme theory developed from an analysis of our realist causal propositions [3]. The resulting Theory of Change (ToC) Logic Model included three design components, namely: sustained health home visiting; family and community integrated service development; and infrastructure support [2]. The three design elements were further developed for inclusion in: 1) a Working with Vulnerable Families Business Case, and 2) Child and Family Health Planning Priorities (**Table 2**). Importantly the design included population, system and individual-level health and social care elements.

During 2014 the Inner West Sydney District collaborative planning for child and family health and wellbeing was extended to focus on improved outcomes for all children and their families. At the time of the launch of the NSW Integrated Care Strategy in March 2014, the planning process had identified four strategic themes, namely:

improving system capacity; health and wellbeing promotion; early intervention and supporting place-based initiatives. In addition a detailed outcome framework had been developed based on earlier studies of child and family population-level indicators [4, 5].

This paper will describe the design development for an integrated care initiative for vulnerable families including children. The design will draw on our earlier causal and programme theoretical work, the 2013 collaborative design for vulnerable families, and the 2014 NSW Government policy framework for integrated care [2, 3, 6]. The research is part of two ongoing programmes of research and programme development that seeks to 1) build and confirm a theory of "Neighbourhood Context, Stress, Depression, and the Developmental Origins of Health and Disease (DOHaD)" [7]; and 2) strengthen the delivery of well child care through mixed method theory building and the application of interagency policy and program interventions. The work was undertaken during 2014 and 2015 with the integrated care initiative commencing July 2015.

Theory and Methods

As previously described [6, 8, 9], the overall research design is a longitudinal, multilevel, critical realist design and evaluation of applied programme interventions that seek to break intergeneration cycles of social disadvantage and poor child health and development outcomes and strengthen delivery of well child care. Intervention initiatives were designed and implemented by interagency and community collaborations. In doing so we aimed to move from "explaining underlying social mechanisms to generate social interventions in partnership with the affected populations" [10].

The main research programme will consist of four phases (**Figure 1**). The methodology used for the four phases is reported separately [9]. In summary the four phases are: 1) operationalisation of programme theory and intervention development and planning; 2) evaluation of the interventions; 3) theory testing studies; and 4) dissemination of the findings. In this paper we report on one of the collaborative design projects undertaken in Phase 1: Operationalisation. The operationalisation of causal and programme theory is briefly described in the Results section with **Table 4**. The full analysis will be reported separately.

Critical realism and programme design

As noted above, critical realism provides the philosophical and methodological underpinning to this programme of work. Critical realism seeks to discover the structures (C) and underlying mechanisms (M) that cause empirically observed patterned events or outcomes (O). These events are tendencies that result when certain conditions exist, or remain unrealised if the conditions are absent. Examining the pre-existing structural conditions of a context is therefore important. Critical realism also holds that mechanisms, in natural and social reality, are stratified. Depression (event), in the strata of the self, is governed by physical, biochemical and psychological mechanisms and laws. These mechanisms are not governed by laws

Table 1: NSW Ministry of Health Integrated Care Functional Components.

Functional Component	Key Feature
Patient and carer empowerment	
Engaging the patient/carer in care planning	<ul style="list-style-type: none"> • The implementation of processes and systems that ensure the integrated care plan meets the needs and preferences of patient/carers as defined by patients or carers themselves (shared decision making).
Using patient reported measures in care delivery	<ul style="list-style-type: none"> • The implementation of a system of patient reported measures for enrolled patients that measure both the patient's perceptions of both their care experience and their outcomes, due to the care that they receive. • This includes the timely provision of the information to clinicians/team delivering care to enable shared care planning/shared decision making.
Supporting and promoting self-management	<ul style="list-style-type: none"> • A set of defined care interventions specific to the targeted patient cohort to support self-management. • This also includes strategies to increase capacity for patients and carers to better self-manage their condition.
Building patient/carer health literacy	<ul style="list-style-type: none"> • The implementation of processes and systems (such as training and information) that improve the patient's understanding of their health condition(s), how to maximise their ability to manage it themselves, how/when to access health services and what role they play in managing their health condition(s). • This also includes care plan access, and active participation to the extent possible in care planning.
Patient identification and selection	
Defining local health needs	<ul style="list-style-type: none"> • The set of local health system parameters which broadly identify the types of patients that require the implementation of an integrated care pathway to improve the effectiveness of healthcare delivery (such as potentially avoidable hospital admission, ED presentations, delays in receiving specialist treatment).
Identifying target cohorts	<ul style="list-style-type: none"> • Patient level parameters (such as demographic, e.g. age; clinical, e.g. diagnosis; utilisation, e.g. number of medications; other, e.g. measure of social disadvantage) that define the group of patients that will be targeted/enrolled in the integrated care program.
Developing systematic approaches to risk identification	<ul style="list-style-type: none"> • The standardised approach to risk identification (such as signs of health deterioration) and methodology (such as automated processes in PAS/EMR/EHR) for identification of the targeted cohort of patients who would benefit from an integrated model of care. • The targeted risks and cohorts can vary locally, and can vary over time within locality as programs mature.
Innovative ways of working	
Establishing new business models	<ul style="list-style-type: none"> • The identification and implementation of business models across the continuum of care are being to promote care delivery which improves patient care and experience through improved coordination and integration. • The models sit alongside service models (which operationalize service delivery). • They potentially incorporate financial and/or non-financial elements. • The models may include the selection of alliance partners (such as GPs, NGOs or other government organisations) and investment in new roles, as well as the use of known business models (such as Person Centred Medical Homes or a Commissioning Framework).
Ensuring appropriate and timely access to specialist care	<ul style="list-style-type: none"> • Needs for the identified cohort. • The function may be achieved in a number of different ways (for example, quarantining appointments in hospital based clinics or purchasing services from a telehealth provider).
Shared/joint care planning and management with the patient/carer	<ul style="list-style-type: none"> • The development of shared or joint care planning and care management strategies between the initiator of the care plan, the patient, and other healthcare professionals who are to be involved in the care and service delivery to targeted patients.
Establishing roles focused on organising patient-centred care	<ul style="list-style-type: none"> • The establishment of roles (such as case managers, care navigators, care facilitators) to support the implementation of the integrated care model of care across care settings (such as hospital, primary care, specialist care, community care).
Embedding agreed models of care	<ul style="list-style-type: none"> • The uptake of models of care for patients with specified conditions that are based on evidence based medicine and adhered to by those clinicians seeing targeted patients. • This includes the process of designing and agreeing the models with stakeholders to optimise uptake.

(Contd.)

Functional Component	Key Feature
Primary and Community care as the hub	
Connecting people to their healthcare team	<ul style="list-style-type: none"> The assignment of targeted patients to a clinical provider (individual/practice) whose role is to be the lead clinical provider with responsibility for the shared care plan and initiating communication with other care providers (such as specialist, GP, aged care, community care).
Systematic assessment, review of patients	<ul style="list-style-type: none"> The implementation of a system of standardised assessments, regular patient reviews, and up-loading of relevant clinical metrics by clinical care providers based on developed integrated care pathway protocols.
Building capacity/capability in primary and community care	<ul style="list-style-type: none"> The enhancement of resources (such as care navigators, training programs, care pathways, share care planning tools) in the primary and community care settings to support integrated care delivery to targeted patients.
Information Sharing	
Establishing a trackable cohort list	<ul style="list-style-type: none"> The establishment of an electronic patient list/register that identifies all patients enrolled in the integrated care initiative and enables the monitoring of the patient journey, as reflected through the patient's use of healthcare services.
Establishing shared access to patient information	<ul style="list-style-type: none"> The extent of electronic patient information on enrolled patients available to clinicians across care settings who are delivering the agreed integrated model of care (such as care plans, e-referral, discharge summaries, medication profiles, test results, service events).

Table 2: Design elements of previous planning.

Design Component	Business Case	Child and Family Health Planning Priorities
Sustained Health Home Visiting (SHHV)	<ul style="list-style-type: none"> Antenatal screening and risk stratification Perinatal pathways and coordination Sustained home visiting commencing before birth Second tier allied health and medical services, pathways and coordination Universal maternal, child and family services with proportionate support according to need 	<ul style="list-style-type: none"> Review and strengthen perinatal coordination Strengthen Aboriginal program (Yana Muru) New SHHV in Canterbury LGA focusing on CALD families Enhance SHHV in Sydney LGA focusing on Redfern and Waterloo suburbs Strengthen Tier 2 support services including access pathways
Family and Community Integrated Service Development (FCISD)	<ul style="list-style-type: none"> Integrated service models including wrap-around and family group conference model Targeted parenting programmes Domestic violence intervention High risk infant tracking models "Hub" and "place-based" community building and service coordination Universal family and community capacity building (health and wellbeing promotion) 	<ul style="list-style-type: none"> Interagency collaborative planning Development of interagency models of care for "high need" schools and early childhood centres Commence neighbourhood "hub" development in Redfern social housing estate Enhanced collaborative interagency parenting communication strategy (phone app and web development)
Infrastructure Support (IS)	<ul style="list-style-type: none"> Child and family public health (epidemiology, programming, research and evaluation) System change strategies Service capacity building Project Management and leadership 	<ul style="list-style-type: none"> Child and family epidemiology Evidence-informed programming Evaluation of perinatal referral pathways Study of universal well child care system Web-based health pathway development Development of well child care and psychological trauma workforce training packages Leadership and technical support to interagency planning groups

operating at the level of social activity, but are nevertheless affected by them. Critical realist theories therefore, may explain event mechanisms by antecedent causes, or explain mechanisms operating at one level by those operating at a more basic level. A higher-level mechanism, is said to be emergent from a more basic mechanism. Lay-

der [11] illustrated this layering of reality in his Research Map (**Figure 2**). This study uses a modification of Layder's levels, namely, Self, Situated Activity, Intermediate Level and Macro Level. Mechanisms, emergence, a hierarchy of levels, and pre-existing historical conditions are all central to the critical realist design process described here.

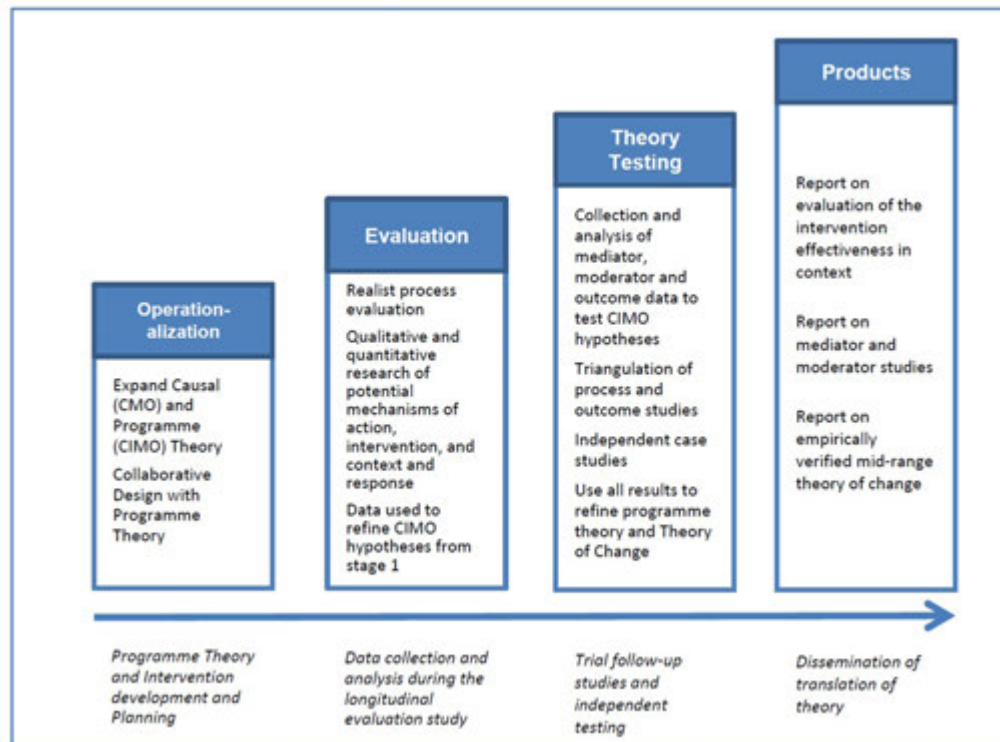


Figure 1: Summary of Research Programme.

	Research Element	Research Focus
HISTORY	CONTEXT	Macro social organisation Values, tradition, forms of social and economic organization and power relations. For example, legally sanctioned forms of ownership, control, distribution; interlocking directorships, state intervention, as they are implicated in the sector below.
	SETTING	Intermediate social organisation Work: industrial, military and state bureaucracies; labour markets; hospitals; social work agencies, domestic labour; penal and mental institutions. Non-work: Social organisation of leisure activities, sports and social clubs; religious and spiritual organisations
	SITUATED ACTIVITY	Social activity Face-t-face activity involving symbolic communication by skilled, intentional participants implicated in the above contexts and settings. Focus on emergent meanings, understandings and definitions of the situation as these affect and are affected by contexts and settings (above) and subjective dispositions of individuals (below)
	SELF	Self-identify and individuals social experience As these are influenced by the above sectors and as they interact with the unique psychobiography of the individual Focus on the life-career

Figure 2: Research Map [11].

Realist causal propositions are expressed in terms of mechanisms (M), context (C), and outcomes (O). The MCO propositions in our previously reported theory [1] are in the MCO form proposed by Danermark and colleagues [12]. For evaluation studies, Pawson and Tilley [13] have proposed a CMO configuration. In realist programme evaluation terminology the mechanism (M) is an intervention mechanism (IM), and not a causal mechanism. Denyer and colleagues [14] draw attention to the importance of specifying the intervention separate from the mechanism and proposed the use of a CIMO-logic (Context, Intervention Mechanism, Outcome). Thus a CIMO is a hypothesis that the programme

theory produces a change (O) because of the action of an intervention (I) on an underlying mechanism (M) operating in particular contexts (C). We will use the CIMO logic in this study and will apply it to the development of the Theory of Change (ToC) logic model (Figure 4).

Realist programme evaluation usually starts with a programme that has been already designed. The approach assumes that whenever a programme is implemented it is testing an existing programme theory consisting of realist programme hypotheses (CMOs). The process of designing a programme intervention using realist causal and programme theory is not well explicated. For the purposes

of this study we have drawn on the work of Keller and colleagues [15] who present a realist design-evaluation framework that combines design theory and realist evaluation.

Collaborative Design

The collaborative design of the integrated care initiative involved: 1) consultation and planning forums; 2) shared outcome planning; 3) collaborative interagency planning; and 4) preparation of a fully funded business plan, ToC and logic model.

The development of a ToC using collective and collaborative processes can be difficult [16]. We used the set of steps proposed by Mackenzie and Blamey:

1. Identification of the long-term outcomes that the initiative seeks to achieve
2. Identification of the interim outcomes and contextual features that will be required to meet these longer-term outcomes
3. Specification of the activities that will be put into place and the contextual requirements to realise these interim outcomes
4. An explicit recognition of the resources that will be required to turn these goals into reality.

The design analysis integrated our earlier causal and programme theoretical work [6], analysis of local child and family population-level indicators [5]; the 2013 collaborative design for vulnerable families [2]; and the 2014 NSW Government policy framework for integrated care. Consequently the critical realist theoretical framework guiding the collaborative effort incorporated 5 elements:

1. historical analysis of the context to theorise the pre-existing social structures and mechanisms [17]
2. proposed design elements of an intervention, stemming from inputs from forums, realist syntheses, interviews and collaborations during 2013 and 2014 [2, 6]
3. proposed design elements arising from an analysis of the NSW Government Integrated Care Strategy
4. the development of a programme theory hypothesising the pre-existing situational conditions and causal mechanisms, and specifying how the proposed intervention would trigger desired psychological, motivational and behavioural responses to bring about change [18]
5. the construction of Theory of Change (ToC) logic model explicating a proposed implementation theory [18].

Ethics

The planning undertaken here did not include human subjects. Ethical approval was not sought. The indicator reports used secondary data and did not require ethics approval. The earlier cited mixed method multilevel studies had ethics approval from the University of New South Wales.

Results and Design

The proposed design elements for the integrated care initiative drew on: 1) collaborative design processes undertaken for vulnerable families in 2013 and the 2014 plan-

ning for a five-year child health and wellbeing plan; and 2) the NSW Ministry of Health Integrated Care Strategy

Shared identification and intake: A population-based approach was proposed for identifying the most vulnerable families, developing cross-agency assessment and referral pathways, and improving hospital maternity services' recognition of the needs of families. The Pathways to Care component included: strengthening of perinatal screening and coordination systems; establishment of a centralised intake system; development of primary care referral pathways using the New Zealand Canterbury HealthPathways Sydney tools; development of a shared family risk assessment tool; building of a electronic medical record tool to support clinicians identifying families; and the building of a database to support the monitoring of outcomes among identified family members.

Care coordination: The design provided for the establishment of a nurse-led family care coordination service model that would support families over a long time period with the intention of bridging the episodic nature of existing family support services. The proposed role was to: a) provide leadership and support in the building of local service networks and referral pathways for vulnerable families; b) liaise with and support service providers to ensure referral to appropriate services in accordance with shared care plan; c) coordinate and track service provision for the identified vulnerable families, including ongoing information coordination for providers; d) provide information, support and referral services for members of the enrolled families. The intention was to make use of all available local government and non-government resources to support the complete needs of families. The component included the trialling of "Patchwork", a care-coordination digital web-based support tool developed in the UK by FutureGov [19].

Evidence informed practice: The overall design included evidence-informed elements: nurse-led sustained health home visiting, wrap-around care, family group conferencing, child and family service centres, and targeted and multimodal parenting programmes. Sustained nurse home visiting was implemented in parallel with the elements described here and provided an important new service for vulnerable families with infants less than 2 years of age. In addition to including evidence-informed elements in the design, the initiative included the establishment of Knowledge Translation Networks that would identify and promote the use of evidence-informed practice.

General Practice engagement and support: the engagement of families with a general practice, and supporting those general practices, was identified as a priority. The intention was to encourage families to have a general practice "health home". An important objective of this component was to reduce emergency department and hospital admission for ambulatory and primary care sensitive conditions. The Australian Commonwealth funded Medical Benefits Scheme (MBS) is premised on the central coordinating role of family physicians in general practice. This component of the design sought to ensure that families had access to all available financial subsidies for their health and social care.

Table 3: Integrated Care Programme Design Elements.

Design Component	Inner West Sydney Collaborative Design	Ministry of Health Integrated Care Policy	Design Elements
1 Shared identification and intake	Strengthen existing perinatal screening and coordination system through review, training and monitoring High risk infant tracking models	Identifying target cohorts Developing systematic approaches to risk identification Establishing a trackable cohort list Establishing shared access to patient information	Shared identification Shared risk stratification Pathways to care Shared intake systems
2 Care Coordination	Strengthen existing perinatal screening and coordination system through review, training and monitoring Strengthen Tier 2 support services Integrated service models including wrap-around and family group conference model High-risk infant tracking models	Engaging the patient/carer in care planning Supporting and promoting self-management Using patient reported measures in care delivery Ensuring appropriate and timely access to specialist care Shared/joint care planning and management with the patient/carer Systematic assessment, review of patients Connecting people to their healthcare team	Patient centered care Strength-based care coordination Facilitated access to specialist care Shared care planning Shared assessment and review of patients Wrap around connecting people to health and social care team
3 Evidence informed practice	Strengthen current SHHV by training, resourcing, management support Integrated service models including wrap-around and family group conference model Targeted parenting programmes		Sustained Health Home Visiting Wrap-around service model Family Group Conferencing Targeted Parenting Programmes
4 General Practice engagement and support		Connecting people to their healthcare team Systematic assessment, review of patients Building capacity/capability in primary and community care	Connecting families to general practice “health home” Supporting general practice to engage and support families Capacity building of general practice
5 Family Health Improvement	Review and strengthen universal services Targeted parenting programmes Universal family and community capacity building	Building patient/carer health literacy	Universal family health literacy Parent education and support programmes Sector-wide capacity building
6 Place-based initiatives	Implement new tiered model of SHHV in Canterbury, Redfern and Waterloo Integrated service models including wrap-around and family group conference model “Hub” and “place-based” community building and service coordination	Engaging the patient/carer in care planning Defining local health needs Connecting people to their healthcare team Building capacity/capability in primary and community care Establishing shared access to patient information	Place-based initiatives in City of Sydney and City of Canterbury/Bankstown Integrated care pilot projects to include: local needs analysis, consumer consultation, “service hub”, wrap-around service provision, family group conferencing, community building and service coordination
7 System Change	Strengthen existing perinatal screening and coordination system through review, training and monitoring	Establishing new business models Establishing roles focused on organising patient-centred care	New business models Strengthen existing perinatal screening and coordination system

(Contd.)

Design Component	Inner West Sydney Collaborative Design	Ministry of Health Integrated Care Policy	Design Elements
	Review and strengthen existing perinatal screening and coordination system project management and leadership Sector capacity building projects System change projects	Embedding agreed models of care Defining local health needs	Shared outcomes, assessment tools, models of care, and evaluation Sector capacity building projects System change projects
8 Child and family Outcomes	Child and Family public health (research, programme, evaluation)	Using patient reported measures in care delivery	Patient reported measures
9 Evaluation	Child and Family public health (research, programme, evaluation)	Defining local health needs	Critical realist evaluation Population outcome evaluation

Family Health Improvement: The purpose of this component was to strengthen the delivery of public health and preventive health measures to families through the service network and general practice. Sector capacity building projects were proposed that would build on concurrent local initiatives including: a parenting communication initiative (“Love Talk Sing Read Play”) and a well childcare sector capacity building project. The intention was to also include preventive health measures into family care plans. Health protection measures for families were also identified as important. The design made provision for enhanced immunisation and healthy housing initiatives.

Place-based initiatives: The design assumed that for service integration to be successful it needed to be locally derived within a well organised primary and community sector. The design proposed two place-based initiatives within the cities of Sydney and Canterbury-Bankstown. The design called for the trialling of wrap-around care in the place-based projects. The full nature of the local initiatives was not detailed in the design with intention of ensuring that they would be locally developed through community and consumer consultation.

System Change: The development of the integrated care design had occurred in the context of a strong cross agency collaborative partnership. The partnership was at that time developing a five-year Child Health and Wellbeing Plan and the integrated care initiative provided an opportunity to demonstrate many of the system change elements included in that plan. The integrated care initiative proposed that opportunities for shared planning, commissioning and evaluation be explored. A number of policies, tools and practices were identified including: informed consent to share information with partners, person-centred care, branding and promotion, web-based and social media tools, client and family self-assessment, robust and trusted privacy, and skilled and well-supported “health home” general practices. The proposal also sought to explore more significant system changes including: cross-agency “task group” models of care; funding and performance agreement changes to ensure shared outcomes in contracts; joint service delivery teams with shared accountability structures; and joined-up entities or new shared-purpose organisations.

Child and family Outcomes: The design identified the importance of having an outcome focus and included the monitoring of separate child and family outcomes. Included in this were several new initiatives that were considered central to integrated care, including: a shared outcome framework, patient reported outcome measures, patient reported experience measures, electronic medical record data-linkage projects, and population outcome monitoring.

Evaluation: The designed initiative was a “complex intervention” and consequently the evaluation framework drew on Medical Research Council guidance for evaluation of complex public health interventions [20–22]. As noted above, the overall research design is a longitudinal, multilevel, critical realist evaluation of applied programme interventions that seek to break intergenerational cycle of social disadvantage and poor child health and development outcomes. MRC guidance argues that only through close scrutiny of causal mechanisms is it possible for evaluation to contribute to developing more effective interventions, and provide insights into how findings might be transferred across settings and populations. Consequently a critical realist mixed method approach was chosen to examine the quantity and quality (or process) of what was actually implemented in practice, the context, the mechanisms and seek to answer the question why [13].

Programme Theory

We have previously published the Programme Theory informing this design [3]. It is presented here to assist readers’ understanding of the design process.

Theory of Change (ToC)

The overall design retained the four strategic themes of the local collaborative design process (i.e. improving system capacity; health and wellbeing promotion; early intervention and supporting place-based initiatives). The place-based initiatives, system change, and health and wellbeing strategies were proposed to be implemented using a co-design approach with local communities and interagency partners. Consequently detailed ToC logic models were not developed components related to those interagency strategic themes.

Table 4: CIMO Propositions.

Theorised Contextual Conditions (Fig. 2) [C]	Present contextual mechanisms activated [C _M]	Proposed Intervention Design Elements (Table 1) [I]	Postulated Intervention Programme Mechanisms (Table 1) [M _p]	Postulated psychological, motivational and behavioural Outcomes [O]
Self – Self-identity and individual's experience				
Lack of partner and family support, Distrust of services, Limited treatment access	Stress mechanism activated causing anxiety and depression	Friendship and family support, Professional support, Medication, Treatment	• Activate mediating mechanisms of family, peer and professional support to strengthen and build trusting relationships with peers, family and clinicians through SHHV and FCISD Design Components.	Decreased depression and anxiety
Lifetime trauma, Loss, Being alone, Isolation	Stress mechanism activated arising from mismatched expectations, and loneliness	Family and peer support, Home visiting, Telephone support		Increased perceived support
Situated Activity – Face to Face activity				
Services unavailable or poor access, Services not trusted, Services not skilled	Absence of trusted professional support mechanism	“wrap-around” services, Family Conferences, Workforce training	• Activate services mechanisms that are client, peer and neighbourhood focused, and trauma and evidence informed through FCISD and IS Design Components.	Improved perceived access to skilled and trusted services
Community distrust, Low social capital and cohesion, crime, unemployment	Absence of trusted neighbourhood and community support mechanism	“wrap-around” services, Family Conferences, Public health, Social work services		Improved perceived support from neighbours and community
Intermediate Level social and service organisation				
Unhelpful intake and referral practices, Lack of service, knowledge and trust	Absence of specialist service support mechanism for front-line professionals	Strengthened pathways and design Collocation of services	• Activate mechanisms related to trust and confidence with service network, increased local social capital, community trust and community safety	Improved perceived access to services that are “wrapped” around front-line workers
Weak social networks, community trust, community safety, available social services, access to information	Social level stress mechanisms relating to class, position, racism, segregation, crime and neighbourhood decay are activated tending to increase psychological stress	Population and community level interventions in neighbourhoods and communities	• Activate mechanisms relating to improved coordination and access to services and information through FCISD and IS Design Components.	Decrease in psychological stress of individuals and families
Macro Level social and service organisation				
Migration, Mega-malls pull service activity away from neighbourhoods, Urban development	Activation of social level stress mechanisms tend to hinder the activation of social level buffer mechanisms	Population and community level interventions in neighbourhoods and communities	• Activate mechanisms related to increased social level activities in deprived neighbourhoods.	Increase in perceived social level buffers
Immigration policy, Racism, Media policy, Global market, Settlement patterns, Ethnic bonding networks, Access to services	Migrant related social level mechanisms including acculturation, cultural practices and integration tend to decrease social level stress	Ethnic and cultural specific community and population level interventions	• Activate mechanisms related to increased migrant related social activities among ethnic populations through FCISD and IS Design Components.	Increase in perceived migrant social level buffers

Note: SHHV-Sustained Health Home Visiting; FCISD – Family and Community Integrated Service Development; IS-Infrastructure Support.

By contrast the interagency partners sought to develop a ToC Logic Model that would guide the implementation of the early intervention and clinical aspects of the initiative. That ToC was particularly relevant for the 1) identification, 2) care coordination and 3) evidence-informed practice components of the design. It also sought to inform the clinical elements of the place-based projects. The ToC is shown at **Figure 3**.

Prior to implementation in July 2015 a full Logic Model of the overall design was constructed to inform NSW Ministry of Health monitoring of the implementation. An adaption of that logic model is shown at **Figure 4** with the inclusion of identified interventions and programme mechanisms.

Discussion

In designing an integrated care initiative for vulnerable families we have drawn on our previously reported empirical studies, the translation of causal theory to programme theory, collaborative design processes, and the integrated care policy elements advanced by the NSW Ministry of Health. Critical realism has provided the methodological underpinning of this programme of work and has assisted to explicate both the contextual conditions and the underlying causal and programme mechanisms. Consequently we have been able to move from our earlier theoretical models toward the design of whole of health and social care system interventions.

In so doing we have moved from causal and programme mechanisms at the individual level toward mechanistic propositions relating to service systems and providers. Those situated activity – face to face activity;

and intermediate level social and service organisational mechanisms, continue to highlight the important of trust and willingness to share power. Thus the development and implementation of system change initiatives, such as general practice focused “health homes” and interagency “task groups” will be very reliant on approaches to sharing power and building trust between actors. To address these challenges the design has moved beyond the usual integrated care components of cohort identification, risk stratification and care-coordination to address the underlying programme mechanisms of trust and power sharing. Strong partnerships with general practice, and social and education sector partners, is critical to the success of initiatives for children and families. True power sharing is difficult for health sector actors and will remain a challenge for the integrated care initiative described here.

The design seeks to address not only intergenerational cycles of violence, family dysfunction and psychopathology, but also the social determinants of health as described in our earlier empirical and theoretical work. Thus throughout the design attention has been given to: meeting all the material needs of families, improving access to services, reducing family social isolation and marginalisation, building local social networks and community cohesion, and improving community health and life-skill literacy.

Central to the initiative reported here is the strong interagency collaborative and the development of a shared outcomes framework. The final funding proposal included significant contributions from the local primary care agency, Family and Community Services NSW, non-government partners and academic institutions. A

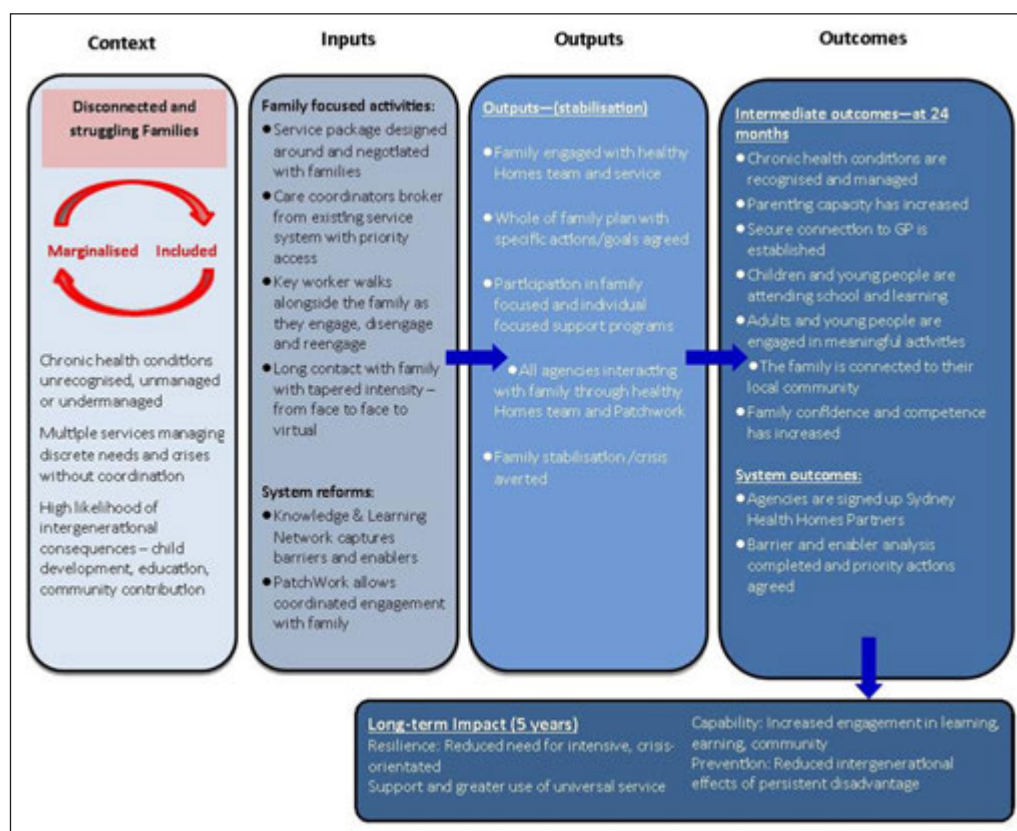


Figure 3: Theory of Change – Early Intervention and Clinical Elements.

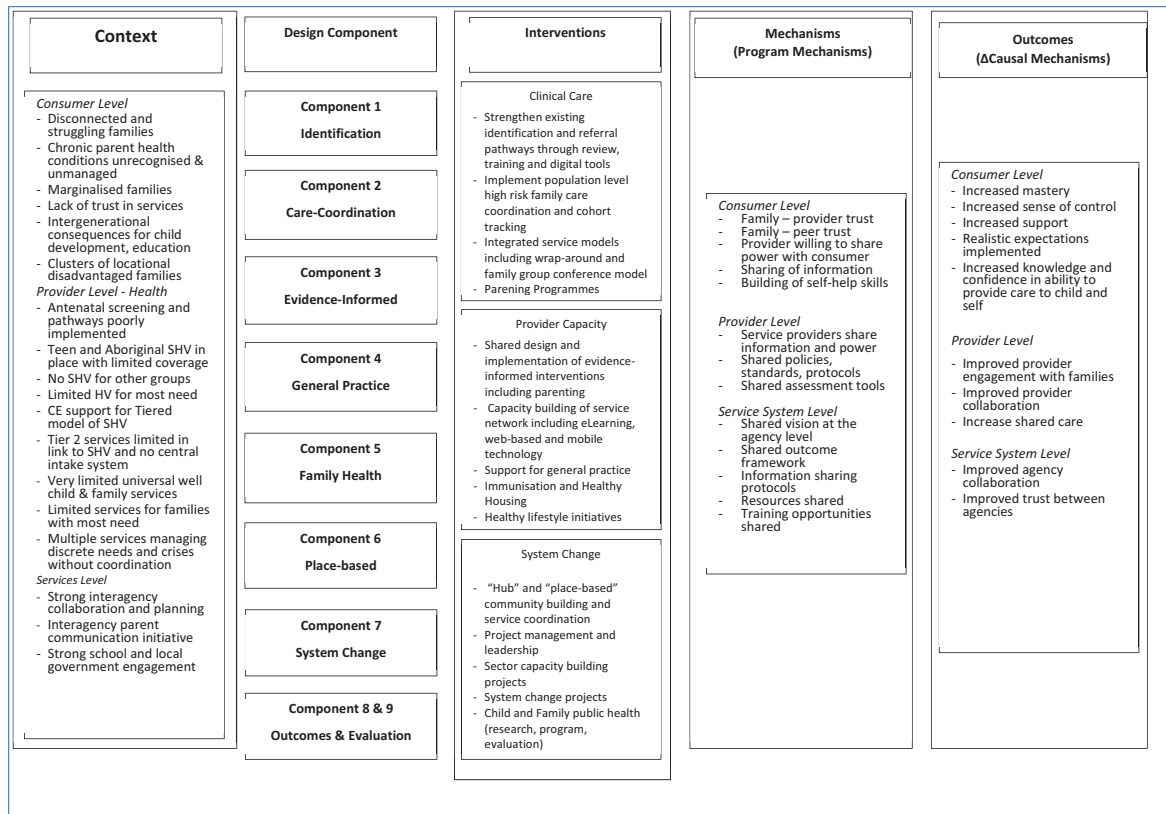


Figure 4: ToC Logic Model.

limitation was the lack of input from the Education sector which was attributable to restructuring of that sector at the time of design preparation. The consequence of this limitation is that the design has not fully explored the causal mechanisms operating within the school setting or the programme possibilities that might be operationalised through those settings. For example, the family-school dimension was not examined and consequently the potential of school initiated family support strategies are absent from the design.

A further limitation was the strong health sector focus despite the collective approach to planning. This can be attributed to the NSW Health integrated care tendering process, which was focused on initiatives for chronic health conditions. Despite this constraint, the final design was able to incorporate strong social care elements that took the design beyond the boundaries of the health sector. The underlying programme theory for the integrated care design remains tentative and will require further explication as part of the evaluation design.

The design propositions developed followed the context-intervention-mechanism-outcome (CIMO) logic advanced by Denyer [14]. That approach was extended beyond the theoretical to be included in the overall logic model. Thus the final logic model included both implementation theory and programme theory elements as proposed by Blamey and Mackenzie [18]. The value of considering and analysing the underlying causal, implementation, and programme mechanisms has been that consideration was given to questions of "why" and "how". Consequently the design sought to build "mutually supporting" activities that would maximise the chances of

success. Thus the analysis of how mechanisms operate in a context can help researchers to look out for, and establish potential areas of impact, through theorising about, and then establishing its causes. This can then facilitate the further refinement and improvement of programme design and implementation.

Conclusion

The design study described advances our earlier empirical and programme design studies toward the implementation of a whole-of-government integrated health and social care initiative. That initiative was designed as a cross-agency care coordination network that would ensure that vulnerable families: had their complex health and social needs met; kept themselves and their children safe; and were connected to society. In so doing we aim to break intergenerational cycles of poverty, violence and crime, poor education and employment opportunities, psychopathology, and poor lifestyle and health behaviours, through strengthening family resiliency, improving access to services, and addressing the social determinants of health and wellbeing.

Reviewers

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Competing Interests

[[COMPETING INTEREST STATEMENT TO BE PROVIDED]]

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RESEARCH AND THEORY

Implementation, Mechanisms of Effect and Context of an Integrated Care Intervention for Vulnerable Families in Central Sydney Australia: A research and Evaluation Protocol

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Introduction: In March 2014, the New South Wales (NSW) Government (Australia) announced the NSW Integrated Care Strategy. In response, a family-centred, population-based, integrated care initiative for vulnerable families and their children in Sydney, Australia was developed. The initiative was called *Healthy Homes and Neighbourhoods*. A realist translational social epidemiology programme of research and collaborative design is at the foundation of its evaluation.

Theory and Method: The UK Medical Research Council (MRC) Framework for evaluating complex health interventions was adapted. This has four components, namely 1) development, 2) feasibility/piloting, 3) evaluation and 4) implementation. We adapted the Framework to include: critical realist, theory driven, and continuous improvement approaches. The modified Framework underpins this research and evaluation protocol for *Healthy Homes and Neighbourhoods*.

Discussion: The NSW Health Monitoring and Evaluation Framework did not make provisions for assessment of the programme layers of context, or the effect of programme mechanism at each level. We therefore developed a multilevel approach that uses mixed-method research to examine not only outcomes, but also *what is working for whom and why*.

Keywords: process evaluation; theory driven evaluation; critical realism; complex intervention; translational social epidemiology

Introduction

In March 2014, the New South Wales (NSW) State Government of Australia released the NSW Integrated Care Strategy to transform the delivery of care for patients, improve their health and wellbeing, and minimise costs associated with fragmentation of care delivery across the hospital and primary care sector. This was to be achieved by: “a) focusing on organising care to meet the needs of targeted patients and their carers, rather than organising services around provider structures; b) design-

ing better connected models of health [and social] care to leverage available service providers to meet the needs of our smaller rural communities; c) improving the flow of information between hospitals, specialists, community and primary care providers; d) developing new ways of working across State government agencies and with Commonwealth funded programs to deliver better outcomes for identified communities; and e) providing greater access to out-of-hospital community-based care, to ensure patients receive care in the right place for them” [1].

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The associated NSW Government's Integrated Care Strategy funding enabled the establishment of an integrated care initiative called *Healthy Homes and Neighbourhoods (HHAN)*. The Initiative was designed as a population-based, family-centered, care-coordination network that functioned across agencies to assist vulnerable families to navigate the health and social care system, to keep themselves and their children safe, and in doing so, promote social cohesiveness [2]. The design was based on an earlier programme of research and collaborative design to support vulnerable families [3].

The intervention

HHAN is intended for vulnerable families with children unborn through to 17 years, whose complex health or social care needs impact on their ability to parent effectively and participate in community life. The intervention was designed to improve adult members' participation in the social and economic life of the community through integrated management of their complex health and social conditions. In turn, the initiative benefits child members of the family by minimising the impact of adult complex health conditions on their safety, health, development and wellbeing. By employing a dyadic, or family-partnership approach, the intervention aims to interrupt complex intergenerational cycles of disadvantage, psychological trauma, underdeveloped parenting and associated poor health and development outcomes (**Figure 1**). The person-centred intervention is supported by other components that function at professional and organisational levels (see Box1).

Box 1: Healthy Homes and Neighbourhoods Key Features.

Healthy Homes and Neighbourhoods

The Healthy Homes and Neighbourhoods Integrated Care Initiative uses a stratified population-based approach to address the needs of families who are experiencing adversity, while supporting parallel interventions for families more generally. The approach to identifying the most vulnerable families who are disconnected from key services has been developed using existing perinatal risk-assessment systems, developing new cross-agency assessment and referral pathways, and improved hospital recognition of the needs of families using an e-health solution.

The initiative has the following key features:

1. Multiple core and non-core agencies **working together over a sustained period of time** (i.e. 5 years) with families with complex health and social needs
2. Co-design and co-production of the initiative in **partnership** with families and service partners
3. **All the needs of enrolled families are in scope** for the intervention, including housing, employment, income support and legal advice
4. An **early intervention and public health approach** to interrupting cycles of family disadvantage, poor health and psychological trauma
5. A **focus on efficiency** through the maximum use of, and leverage from, existing family, societal and government resources, including Medicare scheduled services

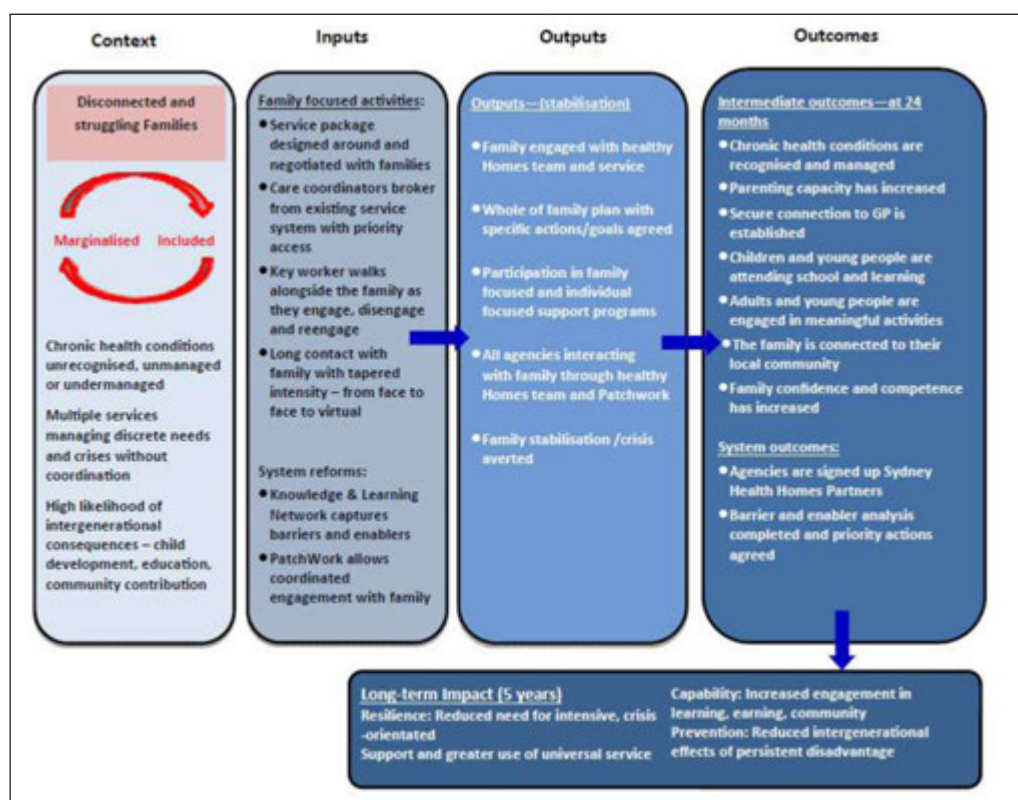


Figure 1: Theory of Change – HHAN Early Intervention and Clinical Elements.

6. Use of **evidence-informed integrated care methods** by service partners, including family case conferencing, and 'wrap-around' care delivery
7. Encouraging families to have a **'health home'** for all their health needs and supporting progress towards self-efficacy
8. **Providing a supporting structure to general practice** providers to care for families that are often seen to be 'too difficult'
9. Development and implementation of **shared assessment tools and referral criteria**
10. Implementation of **family assessment and engagement tools** that can be used over the long-term to monitor the health and wellbeing of family members

A central element of the initiative is targeted long-term sustained cross agency care coordination. The design acknowledges the need for significant system redesign and commitment from partners. The initial model required a care coordination team with both project-funded and partner-funded components as a means of ensuring sustainable 'collaboration'. The initiative also includes local elements through deliberate recruitment of families and service partnerships in the City of Canterbury and City of Sydney local government areas. This last component enabled the development of 'demonstration-site' place-based partnerships with local general practice, schools, family support agencies, local government, religious and faith-based organisations and community members.

NSW Health Monitoring and Evaluation Framework

The programme of research which informs the development of the HHAN research and evaluation protocol is underpinned by the NSW Health Integrated Care Strategy Monitoring and Evaluation Framework [1]. That Framework proposes both formative and summative evaluations, detailed in **Table 1**.

The NSW Health Framework was updated in 2016 [4] to include state-wide approaches to identify integrated care cohorts that would enable tracking of patients across the continuum of care and assessing outcomes through health record linkage. The updated Framework also included a refined set of process indicators. The NSW Health Monitoring and Evaluation Framework is focused on the evaluation of the intervention theory with no explicit attempt to evaluate either context or programme mechanisms. Thus for the programme of research described below we will: 1) explicate implementation (intervention) theory as part of the NSW Health implementation evaluation and 2) examine programme theory using critical realist research and evaluation methods. Identifying contextual and programme mechanisms in the programme theory will be important for assessing the validity of claims made about what works, for whom, under what conditions, and why, and how what works or does not work may be attributed to the HHAN initiative.

UK Medical Research Council (MRC) Framework

Apart from adhering to the local standards recommended by the NSW Health Monitoring and Evaluation Framework [1], the research and evaluation framework for HHAN also aligns with recommendations proposed by the UK MRC Framework. The vast majority of care provided in the context of achieving integrated care is undertaken by care deliverers (professionals and informal caregivers) and includes multiple single interventions which interact with each other. That care is characterised as complex care or complex interventions [5]. The MRC model has proven to be a useful framework for developing, testing and implementing complex interventions [5]. As early as 2000, the UK MRC introduced a framework for evaluating complex interventions recommending sequential phases of development, feasibility testing and evaluation, culminating in the estimation of effect size via a randomised controlled trial [6]. The 2008 update provided a four-phase, cyclical framework of development, feasibility/piloting, evaluation, and implementation (**Figure 2**) [5].

A limitation of the MRC Framework as it stands, is that it relies only on independent verifiable observations. As a consequence, the MRC Framework does not allow for the essential inductive, and abductive, process required for developing complex interventions to fit context. Critical realist, and theory of change, research and design processes, enable theory driven design to be developed that takes historical and current context into account.

The research and evaluation protocol described here will draw on the NSW Health Integrated Care Strategy: Monitoring and Evaluation Framework [1, 4], the 2008 UK Medical Research Council (MRC) Framework for complex interventions, and our previously reported critical realist methodology [8]. We have modified our previously reported critical realist methodology to better align with the 2008 MRC Framework. The methodology described here is designed specifically for an integrated care audience. As with all mixed-method research protocols it is also appropriate for the early section to have a strong methodological content.

The research and evaluation protocol is integrating a number of quite disparate and conflicting methodological approaches including critical realism, evaluation of complex interventions, theory of change, logic models and improvement science approaches. As such, we will introduce these in the next section, before describing our adapted evaluation framework and methods.

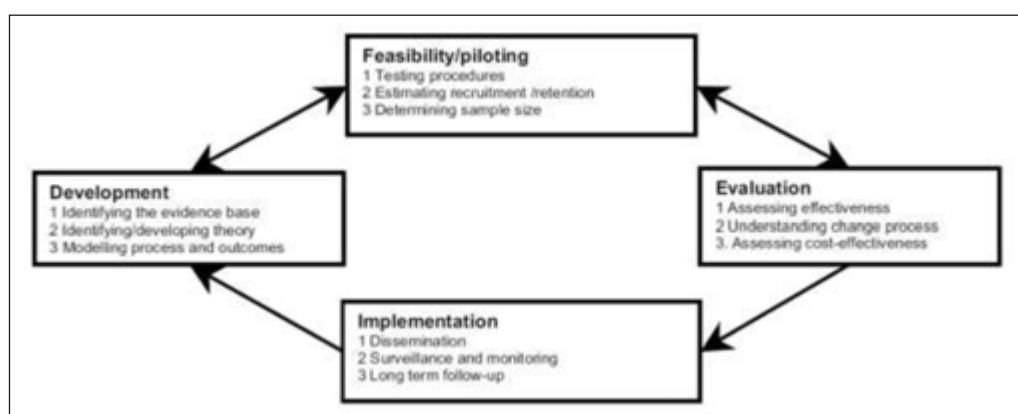
Theory and Methods

Critical Realism

As a contemporary philosophy of science, critical realism draws from both post-positivist and interpretivist traditions and views reality as an open system. It therefore acknowledges the fallibility of our understanding of reality. In keeping with post-positivist tradition, critical realists draw a distinction between the intransitive domain where reality exists independent of our knowledge of it, and the transitive domain which considers our generation of theories to derive incomplete understandings and knowledge about reality. Drawing on an

Table 1: NSW Health Monitoring and Evaluation Approach [1].

Key steps	Outputs
Formative evaluation components	
Discovery and planning through program logic	<ul style="list-style-type: none"> Detailed program overview of activities and expected outcomes Key assumptions about how change will occur Anticipated outputs and outcomes
Development of relevant indicators	<ul style="list-style-type: none"> Process indicators and metrics recognising that both local and state-wide indicators exist Progressively develop new data collection mechanisms
Development of purposeful road maps	<ul style="list-style-type: none"> Develop road map milestones based on key evaluation questions emerging from the logic maps Develop milestones that reflect indicators, both qualitative and quantitative, that allow assessment of actual outcomes relative to expected outcomes
Definition of key functional components of integrated care	<ul style="list-style-type: none"> Common framework of functional components to facilitate the development and capture of core indicators
Summative evaluation components	
Design of reporting approach	<ul style="list-style-type: none"> Quarterly output/outcomes reports for discussion at local health district (LHD) performance meetings and integrated care governance committees Annual outcome evaluation reports
Identification of data sources	<ul style="list-style-type: none"> Identify all monitoring and evaluation data sources Use routine data collection wherever possible
The philosophy of continuous improvement	<ul style="list-style-type: none"> Continuous improvement strategy based on Plan-Do-Study-Act (PDSA) cycle approach Changes to program direction or arrangements based on reflection on monitoring results and outcome reports – what is working and what is not
Detailed design and execution of evaluation approach	<ul style="list-style-type: none"> Appropriateness, effectiveness, efficiency assessed at different stages of the program to determine immediate, intermediate and longer-term outcomes

**Figure 2:** Key elements of the development and evaluation process [7].

interpretivist tradition, critical realists view the process of developing scientific knowledge and theory as socially constructed—political, historical and imperfect [9–12].

A second tenet in critical realist ontology proposes that three inter-related domains make up reality. These domains are (1) the real—where entities are said to possess structures and mechanisms that have generative powers whether these are actualised or not; (2) the actual—where entities under certain conditions actualise the powers and mechanisms they possess to produce events, but that these may or may not be empirically observed; and (3) the observed or empirical—where entities actualize their

powers and mechanisms under given conditions to produce events that are observed and experienced [10]. Thus, critical realism does not accept empirical observations as the only domain of reality that needs explanation. It seeks to include explanations about how entities are structured, their mechanisms and the conditions needed to activate those mechanisms.

Theory driven approaches

We have also drawn here on the work of Blamey and Mackenzie who compared Theories of Change and Realist approaches to evaluation [13]. Put simply, Theory of Change (ToC) research focuses on intervention theory, while realist

evaluation examines programme theory. Citing Weiss [14] they define “[intervention] theory” as “what is required to translate objectives into ongoing service delivery and programme operation” and “programme theory” as “the responses of the people to programme activities”.

Blamey and Mackenzie [13] propose that the ToC approach be used as a means of explicating [intervention] theory for the purpose of programme planning, improvement and the development of robust monitoring systems at a whole programme level; while Realistic Evaluation approaches be used to examine in detail aspects of the most promising programme (mechanism) theories. In this study protocol we will use both approaches (**Figure 3**).

Philosophy of continuous improvement

In keeping with critical realist research methods we propose to use the Realist Evaluation Cycle as proposed by Pawson and Tilley [15]. Critical realism pays particular attention to studying the historical nature of the conditions or context within which the intervention is implemented. Consequently the approach we will take will involve base-line critical realist studies that examine the context in the early phase of implementation [16]. This is to enable before and after comparisons to be made so as to establish and track ongoing change being introduced and taking place within the HHAN intervention. Thereafter, the realist evaluation cycle will be used to identify the causal pathways that may explain the outcomes being produced and to surface unexpected outcomes which indicate the need to make further modifications to the way the integrated care initiative is organised. This approach is also in keeping with action research methods and the quality improvement “Plan, Do, Study Act” (PDSA) cyclic approach to adaptive management of programmes. Consequently we will also explore in the following methodology the application of PDSA methodology within a critical realist evaluation approach.

Protocol Overview

In summary, we have drawn on the above research and evaluation frameworks and theories to inform our adapted research and evaluation protocol for HHAN as shown in **Figure 4**.

The double arrows used in the original MRC Framework are intentional and denote the iterative nature of the development, testing, evaluation, implementation cycle. This is not unlike the constant comparative approach used in emergent theory building approaches such as grounded theory. We believe that all elements of the cycle will influence each other throughout the course of the program. Consequently, we have added additional arrows to the model above (**Figure 4**). The 2008 MRC Framework provided a four-phase, cyclical framework of development, feasibility/piloting, evaluation, and implementation [5]. We have adapted the MRC Framework phases to our previously described operationalisation, contextualisation and evaluation phases as follows:

- Development – Operationalisation
- Feasibility/piloting – Contextualisation
- Evaluation
- Implementation.

The phases, methods, projects and activities are summarised in **Table 2**.

Development (Operationalisation)

The purpose of the Development Phase is to make explicit what we are trying to do, the outcomes we are aiming for and how we intend to bring about change. To achieve this it is essential that the intervention has a coherent theoretical base. In the case of an integrated care intervention the theoretical base will be layered and draw on not only evidence of effective interventions but also effective organisation in the form of a relevant programme, process or mechanistic theory [19]. In the adapted framework we have identified the importance of undertaking collaborative design processes in the Development Phase. The elements are:

1. Identify layered domains or strata
2. Identify mechanisms and evidence base
3. Undertake Collaborative Design
4. Define intervention and program theory
5. Modelling process and outcomes.

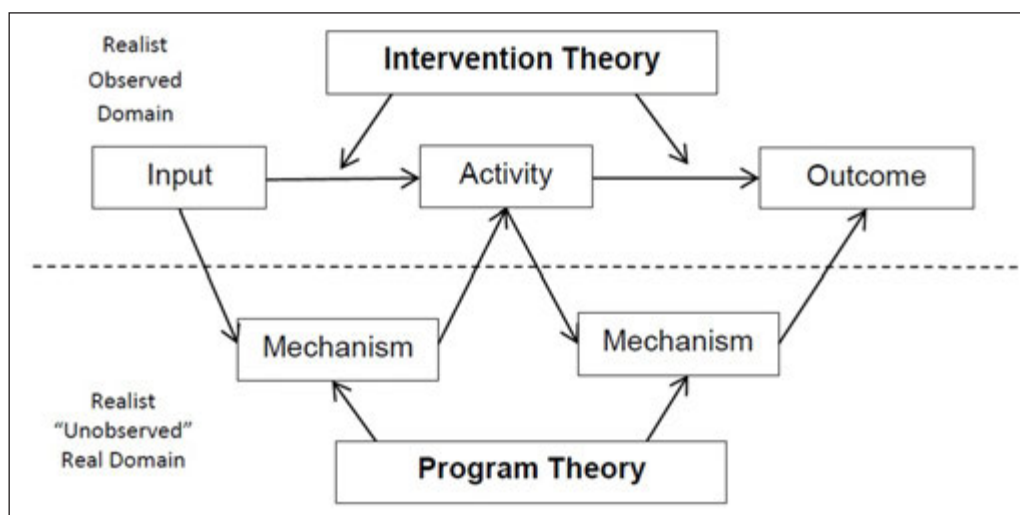


Figure 3: Intervention and Program Theory.

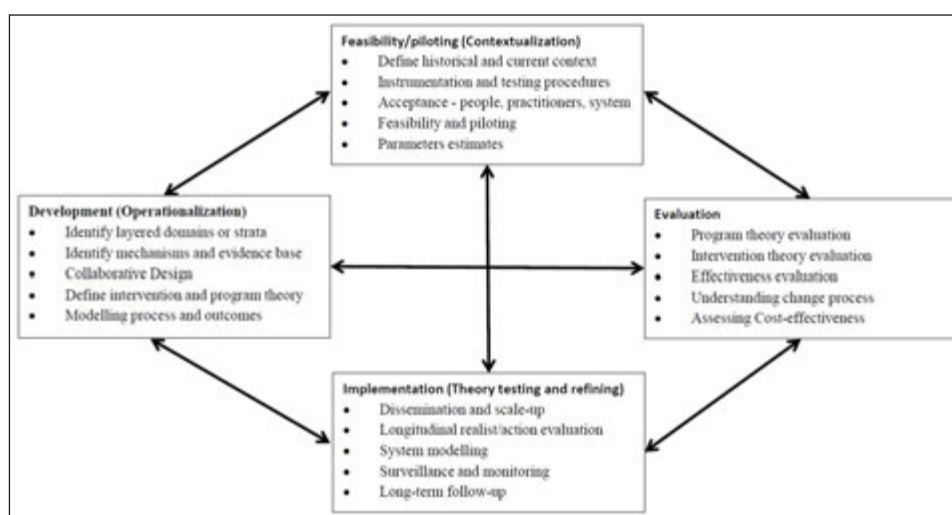


Figure 4: Key elements of the development and evaluation process, adapted from [7].

Our critical realist methodology for the Development (Operationalisation) Phase has been previously described [8], and we have reported the two design studies that led to the development of this integrated care initiative for vulnerable families [2, 3]. As part of that process we specified the layered domains and identified prospective intervention and programme theory from relevant published theories, meta-syntheses and realist synthesis [18]. The resulting Theory of Change and Logic Models have been previously reported [2].

The Critical Realist research cycle, and both the MRC and NSW Health Evaluation Frameworks, make it clear that the Development Phase is dynamic. Throughout the research and evaluation process the Logic Model will be reviewed. The original two design studies identified a number of evidence-based clinical interventions, including: perinatal psychosocial screening, sustained nurse home visiting, targeted parenting programmes, wrap-around care, and family group conferencing. The integrated care design allowed for other “evidence-based” interventions to be introduced. We propose, therefore, to undertake a number of further Development Phase studies as the intervention is implemented. They will include, but not be limited to: systematic and realist reviews of perinatal psycho-social interventions; universal child and family services; early childhood literacy; parental health literacy; multidisciplinary teams; and place-based child and family initiatives.

The Development (Operationalisation) Phase includes modelling of process and outcomes as part of the development of the Theory of Change and related Logic Models. That analytical process identified the need for measures of context, mechanisms and outcomes. Not all of those measures were available at the time of the design development. Importantly NSW Health had not identified the monitoring and evaluation data sources necessary to assess medium and long-term outcomes. The development of relevant patient and programme indicators is described in the next section.

Feasibility/piloting (Contextualisation)

The MRC Framework describes the purpose of the feasibility and piloting phase as being to test “procedures for their acceptability, estimating the likely rates of recruit-

ment and retention of subjects, and the calculation of appropriate sample sizes”. Missing from the MRC advice is consideration of the need to study the broader context including: acceptability of the intervention by service providers, and the broader layered service system. Within a layered integrated care intervention the measurement of clinical, process and outcomes indicators is problematic. To enable full piloting to occur it will be necessary to have developed and tested all instrumentation and testing procedures, also giving space to other approaches for evaluating an effect other than using a trial.

In the adapted framework we have identified the importance of defining the context and instrumentation. The modified Feasibility/piloting (Contextualisation) elements are:

- Define historical and current context
- Define instrumentation and testing procedures
- Assess acceptance by people, practitioners, and the system
- Undertake feasibility and piloting
- Determine parameters estimates.

Our critical realist methodology identified the importance of contextualisation of intervention case studies and the subsequent development of data collection tools and approaches in those concrete situations. The integrated care initiative will be evaluated in multiple contexts and system layers. A particular feature of the critical realist approach is the emphasis on studying the full historical and current perspective of the layered context. At a clinical level this involves a comprehensive psychosocial interview. At practitioner, provider and system levels a similar analysis is required. This analysis also has implications for the development of measurement instrumentation.

We have previously observed [8], that it is likely that modifications will be required for interview, focus group, and quantitative instruments to ensure acceptability, appropriateness and validity. For the purposes of our Sydney-based intervention, modifications will be required for data collection from Aboriginal and Torres Strait Islander populations, and those of culturally and linguistically diverse backgrounds. It will also be necessary to modify our data

Table 2: Phases, Methods and Proposed projects and activities.

Phase	Methods	Projects/activities
Development (Operationalization)	<ul style="list-style-type: none"> Identifying the layered domains or strata Identifying the mechanisms and evidence base Undertaking collaborative design Defining the intervention and program theory Modelling the process and outcomes 	<ul style="list-style-type: none"> Building realist causal theory [17] Building realist program theory [18] Designing initiatives for vulnerable families [3] Designing HHAN integrated care initiative [2] Systematic literature reviews Meta-narrative and realist synthesis reviews. Building the detailed HHAN Logic Model.
Feasibility/piloting (Contextualisation)	<ul style="list-style-type: none"> Define historical and current context Define instrumentation and testing procedures Assess acceptance by people, practitioners and the system Determine parameter estimates 	<ul style="list-style-type: none"> Delphi study of HHAN context Define the HHAN intervention indicator KPI data set Define and test HHAN patient reported measures Data-linkage studies including GIS and Epidemiology studies Base-line qualitative and mixed method studies of each HHAN intervention component.
Evaluation	<ul style="list-style-type: none"> Program theory evaluation Intervention theory evaluation Effectiveness evaluation Understanding the change process Assessing cost-effectiveness 	<ul style="list-style-type: none"> Realist qualitative and mixed-method HHAN studies, including: <ul style="list-style-type: none"> Partner-level studies Place-based studies (including practitioners and consumer studies) Quantitative modelling studies of: <ul style="list-style-type: none"> Patient reported measures Data-linkage studies. Consideration of control designs for clinical component.
Implementation (Theory Testing and Refining)	<ul style="list-style-type: none"> Dissemination and scale-up Longitudinal realist/action evaluation System modelling Surveillance and monitoring Long-term follow-up 	<ul style="list-style-type: none"> Longitudinal HHAN intervention evaluation. Including monitoring of KPIs, system modelling, and ongoing qualitative interviews Longitudinal mixed method study, including HHAN PDSA cycles and monitoring of HHAN PRMs.

collection approach where domestic violence and severe psychological or physical trauma has been experienced. Given the emergent longitudinal nature of the research we anticipate that the data collection tools will require modification after each analytical cycle.

The Feasibility/piloting (Contextualisation) Phase will include the following studies or bodies of analysis:

- Baseline study of context using a Delphi-style approach
- Indicator development and instrumentation
- Development of person-centered reported measures (aka Patient Reported Measures)
- Data-linkage studies
- Pilot critical realist case studies

Delphi Study of Context

The aim of this body of research will be to undertake qualitative studies of barriers and enablers that exist for families that either help or hinder their engagement with services. The method will be a triangulated study consisting of Delphi studies, focus groups and individual semi-structured interviews. Senior staff from partner organisations will be identified by the researchers and contacted to par-

ticipate in a Delphi-style panel discussion with 8–15 panel members. The aim of the discussion will be to rank the importance of barriers and enablers in the local context. This information will be incorporated into the creation of two separate interview guides; one for frontline staff which will be conducted in the form of a focus group(s), and individual semi-structured interviews with families.

Development of Indicator Instrumentation

The purpose of the programme of analysis is to develop relevant indicators of context, programme content, mechanisms and outcomes based on the Programme Theory, ToC and Programme Logic. The indicators and metrics will be developed at individual, family, practitioner, agency and programme level. Individual and family level indicators will be drawn from current clinical policy, practice and various Australian research programmes, such as the Longitudinal Study of Australian Children (LSAC) [20], and Australian Early Childhood Census [21]. Child outcomes indicators, for example, will include: Immunisation status, National Assessment Program – Literacy and Numeracy (NAPLAN) [22], Ages and Stages Questionnaire (ASQ) [23] and Strength and Difficulties Questionnaire (SDQ) [24]. Adult indicators will be drawn from those used in

other integrated care initiatives and accepted local clinical practice. The HHAN design identified a number of possible indicators, including: assessments of diabetes, mental health and drug and alcohol use. Practitioner, agency and programme process and outcome indicators will be taken from the Programme Logic Model. Population-level studies will be undertaken using the indicator set and will inform longitudinal spatial-temporal studies of programme impact. The indicator framework will also be used to inform the NSW Health Intervention “Road Map” Evaluation, Person Reported Measures (PRMs), and data-linkage studies (discussed below).

Person reported measures (aka PRMs)

The purpose of the PRMs research programme will be to develop and monitor person reported outcome and experience measures for enrolled family members. A PRMs process will be developed using self-reported survey tools that can be administered either during clinical encounters or by access to web or phone-based data entry. A study of suitable measures will be undertaken and trialled during the first operational year. Health and wellbeing measures for both children and adults will be used. The tools will be used for baseline assessment, experience of the programme and self-reported outcomes.

Electronic Medical Records (EMR) Data-Linkage Studies

This project aims to develop technical and analytical approaches to the use of routinely collected patient information to examine the impact of implemented integrated care initiatives on the early life experiences and the health, development and welfare of infants born in the Sydney Local Health District (SLHD). This will initially involve linkage and the exploration of routinely collected maternal and child health information sourced from the SLHD EMR databases. The project will undertake both epidemiological (such as examination of association between early life experiences and adulthood health outcomes) and health service research using the linked maternal and child health data. The data will be analysed using Geographical Information System (GIS) methods. Those studies will be used to identifying the geographical distribution of the “most vulnerable” families with intergenerational cycles of disadvantage and trauma in SLHD. The analysis will contribute to identify “hot spots” suitable for the place-based interventions proposed in the intervention design. The EMR programme of research will contribute to the development of population-level measures of impact including studies of hospitalisation, Emergency Department and outpatient attendances by both parents and their children.

Baseline Case Studies

The intervention design calls for the progressive implementation of intervention components including: place-based initiatives with wrap-around models of care; family health improvement health literacy projects; general practice and engagement initiatives; strengthened referral pathways; person report measures (PRMs) and system change. For each component of the design, baseline case studies will be undertaken. The case studies will,

where appropriate, use critical realist methodology and will seek to understand what is working, for whom and in what circumstances within the family and practitioner strata of the integrated care initiative. Case study methods will be used to explore and examine the context, intervention, mechanisms and outcomes (CIMO), through in-depth qualitative interviews of clients and practitioners, clinical records, and survey tools. Quantitative tools will also be used including: social network analysis, baseline risk assessment, and PRMs (i.e. self-efficacy and quality of life measures). For the place-based projects baseline community consultation will be also undertaken. The findings of these baseline case studies will inform the studies undertaken in the Evaluation and Implementation Phases.

Evaluation

The complex whole-of-system nature of the HHAN integrated care initiative places significant challenges on the prospect of evaluating the effect and efficacy of the interventions. The 2008 MRC advice proposed the use of: individually randomised trials; cluster randomised trials; stepped wedge designs; randomised consent trials; and N-of-1 designs. Although they focus on evaluating the effect of the intervention, the advice recognised the importance of process evaluation within trials. Moore and colleagues subsequently published MRC-endorsed advice on process evaluation of complex interventions [25] and Richards and Hallberg [26] provided an overview of alternative approaches, including revisiting the use of Bradford-Hill’s thinking on causality. The MRC argues that too many complex interventions are brought to a trial without proper development and feasibility testing, leading to large amount of research waste [27, 28]. Although their model is nowadays established worldwide, adding the realist perspective will reduce research waste [29]. The emphasis on evaluating changes in aggregate measures continues to be criticised by realist researchers [30], and consequently Fletcher and colleagues have recently advanced a realist approach to the MRC Framework [31]. We have previously described a critical realist methodology which will be applied here to the evaluation of the HHAN integrated care initiative [8]. That methodology included: mixed method studies; qualitative case studies; quantitative studies, structural equation modelling, and the use of action research and PDSA cycles [32]. The Evaluation Phase will include the following studies or bodies of analysis:

- Realist Mixed-method studies
- Quantitative modelling.

The possibility of including other evaluation designs is currently under consideration, including: nested individual randomised control trials (i.e. targeted parenting initiatives); population-level spatial-temporal analysis; stepped-wedge designs and single-subject designs.

Realist Mixed Method studies

The initiatives to be evaluated will be complex with likely multiple contexts and layers as described by Layder [33, p 73]. We anticipate that it will be necessary to focus separate evaluation studies on one level and stage of the logic

model (i.e. case-studies). The description of the various contexts will require a full historical and current perspective of the layered context. At the individual client level the contextualisation will entail, for example, a full personal and family history similar to that undertaken in a comprehensive social interview. Where the evaluation is focusing on a situated activity or setting, the documentation is likely to require an exploration of historical pre-existing features of the setting that may themselves be mechanisms with generative power. The methods will be similar to that described above for the Baseline Studies.

Given the nature of the causal and programme theories being investigated we intend to, where possible, focus separate studies on: 1) maternal and family contexts; 2) practitioner contexts; 3) place-based settings; and 4) inter-agency contexts. The pre-existing vertical relationships in the layered system will also be examined. The Partner-level and Place-based studies will have additional elements.

Partner-level studies

These studies aim to understand what is working, for whom and in what circumstances within the implementation of the integrated care initiative at interagency and policy levels. The qualitative component utilises the same methods to those described above for the Realist case studies. The study will explore and examine the context, mechanisms and initiative outcomes (CMO) as experienced by agency and policy participants, through in-depth qualitative interviews, document analysis, and survey tools. The survey tools will include social network analysis and a partnership evaluation tool.

Social network analysis is a method that can be used to identify and map inter-organisational relationships. Interviewees will be asked to complete an online survey in which they nominate other community agencies and organisations with which they collaborated via receipt of referrals, sending referrals to, sharing information about clients, and “working together in other ways.” Respondents can also nominate other agencies not listed in the survey. The nature of those relationships are then described.

Place-base case studies

The aim is to understand what is working, for whom and in what circumstances within the Neighbourhood integrated care initiatives. The methods for the place-based case studies are yet to be fully formulated but will include: participatory research methods, realist mixed method studies with families, practitioners and partner agencies (as described above), local General Practice focused studies, and modelling of local quantitative data, including multilevel and spatial studies. The place-based case studies will by necessity include all four phases of the research framework described here. The development, feasibility, evaluation and implementation phases will all be undertaken with local consumer and practitioner input.

Quantitative Modelling

Quantitative data will be used to evaluate both programme and intervention theory. Those two purposes are quite distinct with the instruments chosen for programme evaluation being derived from both the causal (MCO) and pro-

gramme (CIMO) hypotheses developed in the Development (Operationalisation) Phase, and subsequently modified during the intervention evaluation. Given the longitudinal emergent nature of the evaluation it is anticipated that some quantitative measurements will be added or altered during the course of the evaluations. We consider that addition or amendment of quantitative measures enables more valid testing of the middle range theories.

Modelling of quantitative data within a critical realist evaluation is controversial but supported by realist methodologists Sayer [15, 34–37]. We will use the structural modelling approach recently described by Jamal and colleagues [37]. In keeping with earlier realist studies by Kazi [38] the programme evaluations will use previously validated psychometric instruments as measures of hypothesised mechanisms and outcomes. These could include measures of child development and behaviour, self-reported health, self-efficacy, depression, isolation, and health literacy. We have also previously described critical realist approaches to multi-level spatial modelling, factor analysis and regression studies [39, 40]. We will use those methods to analyse the data-linkage data collections described earlier.

Implementation

The MRC Framework provided advice on the implementation of complex interventions with a focus on dissemination of findings, surveillance, monitoring and long-term outcomes. The Framework also stresses the need for changing behaviour of a wide range of people. Understanding the behaviours that need to change, the factors maintaining current behaviour and barriers and facilitators to change is crucial to inform implementation of any initiative that incorporates behaviour change [7]. The NSW Integrated Care Strategy will provide regular forums for the dissemination of findings at each stage of the intervention. The state-wide and local interagency governance structures will also allow for wide dissemination of learnings across the whole-of-government system. Our focus here will be on longitudinal surveillance, monitoring, outcome measurement, and adaptation of the intervention, based on both formative and summative findings. We have consistently identified the need to use realist continuous improvement PDSA cycles and action research approaches to understand historical and current contextual behaviours in the implementation of the HHAN integrated care initiative. This will be achieved by utilising the multi-level critical realist case studies and NSW Health monitoring to continuously assess and modify the intervention.

Longitudinal Intervention “Road Map” Evaluation

The aim of the longitudinal intervention evaluation is to develop a Roadmap of Program Milestones (RPM) based on key evaluation questions emerging from the logic map and functional components of the design. The NSW Health Integrated Care Strategy: Monitoring and Evaluation Framework [4] proposed the use of both qualitative and quantitative indicators, to allow assessment of actual outcomes relative to expected outcomes. The RPM will be used to identify whether the program is ‘on track’. Key

milestones will be identified that indicate logical progress towards the intended outcomes of the program. The logic mapping allows the key annual milestones to be purposefully identified, and to be updated at the beginning of each year. Analysis of the RPM will be used to support other evaluation components including the critical realist, outcome and enabler studies. The longitudinal study will include regular qualitative interviews with programme managers and stakeholders regarding progress against an agreed set of qualitative indicators that are based on the functional components. The programme stakeholders will also be regularly involved in programme review workshops.

Longitudinal Critical Realist Studies

The aim of the longitudinal critical realist study is to understand what is working, for whom and in what circumstances within the implementation of the integrated care initiative at family, practitioner and agency levels. A longitudinal emergent realist mixed method study design will be used. For the qualitative component, the same methods to those described above for the Realist case studies will be used. The findings of the individual case studies will be aggregated [15].

The Program Theory will be modified based on aggregated findings. Based on the modified Program Theory, semi-structured interview schedules will be developed to further examine proposed mechanisms. The above will be complemented by client and practitioner focus groups to further examine the mechanisms proposed to be operating within the individual family – practitioner configurations. The practitioner and agency CMO configurations will be examined utilising practitioner and agency level interviews and focus groups.

Discussion

When designing the Healthy Homes and Neighbourhoods Initiative we built on a previous programme of mixed method multi-level critical realist empirical research and theory building. The challenge of integrating care for families under stress necessitated a complex design. We have addressed this through adapting and incorporating relevant evaluation frameworks, theories and quality improvement methodologies to inform our adapted conceptual framework for the evaluation of HHAN. To do justice to the complexity of the context, several research methodologies have been integrated in this paper. This may seem like a methodological paper, but the application of these methodologies the complex context of the HHAN program is an essential part of our message in this paper. The consequence of undertaking research in relation to integrated care is that the complexity of the research, and the methodologies required, will increase in relation to that usually applied for singular interventions.

Both the 2008 UK Medical Research Council Framework for evaluating complex interventions, and our previously reported critical realist methodology, provided the tools to enable an iterative approach development, design, testing and continuous evaluation. The reporting requirements of the NSW Health Integrated Care Strategy: Monitoring and Evaluation Framework provided an additional challenge

as did the requirement to use ToC approaches together with a realist methodology.

As discussed earlier, the philosophical paradigms underpinning each approach are different. Both the NSW Health and MRC Frameworks were developed from the “logical positivist” inductive and deductive reasoning traditions with a strong focus on activities and outcomes but little emphasis on process. Fortunately this weakness has been recognised and Moore and colleagues subsequently published MRC-endorsed advice on process evaluation of complex interventions [25].

The use of the term “implementation” in the MRC Framework is problematic as both the NSW Health Monitoring and Evaluation Framework and ToC terminology (below) use the term “implementation” with different meaning. To avoid confusion we have used the term “intervention” where those two frameworks would have used “implementation”. The MRC Framework is primarily focused on the evaluation of efficacy and effectiveness of intervention “content”. By contrast integrated care and realist evaluation approaches are predominantly about process and mechanisms in context respectively. As noted elsewhere those two perspectives can be reconciled with the inclusion of process and realist orientated research methods [25, 41] as demonstrated in this framework.

As observed earlier, similar challenges exist when using the ToC approach to evaluation. We have drawn here on the work of Blamey and Mackenzie [13] who compared Theories of Change and Realist approaches to evaluation. Blamey and Mackenzie [13], proposed that the ToC approach be used as a means of explicating [intervention] theory for the purpose of programme planning, improvement and the development of robust monitoring systems at a macro programme level; while Realistic Evaluation approaches be used to examine micro level aspects of the most promising programme (mechanism) theories.

In program implementation and evaluation, these ontological tenets have implications on how the accounts of integrated care service delivery, and the claims made about their impact, are to be assessed. In this program of research and evaluation, possible threats to validity arising from the accounts developed will be addressed using criteria proposed by realists [42] who view ‘the validity of an account as inherent, not in the procedures used to produce and validate it, but in its relationship to those things that it is intended to be an account of’. The kinds of threats to validity that the HHAN initiative aims to address in practice are those associated with descriptive, interpretive, theoretical, generalisability and evaluative validity as elaborated by Maxwell [42]. A full exploration of realist approaches to validity is not possible here, but it is our intention to ensure each protocol developed under this methodological framework, makes clear the ontological approach to validity that is being used.

Conclusion

Integrated care initiatives are examples of complex interventions in health and social care. The interventions are multi-layered and operationalisation is strongly influenced by both historical and current context. This

aspect alone makes it imperative that the research and evaluation methodology used is post-positive and takes ontologically stratified context into account. The NSW Health Monitoring and Evaluation Framework did not make provision for assessment of context or mechanism of effect. We describe here a multilevel approach, including a continuous improvement approach, through constant comparison and triangulation of mixed method findings. Finally the research and evaluation protocol described here, has utilised the MRC Framework for evaluating complex interventions within a critical realist methodology, thus enabling us to study both mechanisms of effect and context. As such the innovative methodology utilised here is of potential relevance to other researchers facing similar challenges in evaluating integrated care.

Reviewers

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Competing Interests

[[COMPETING INTEREST STATEMENT TO BE PROVIDED]]

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