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Using Normalisation Process Theory to investigate the implementation of school-based oral health promotion

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Despite the considerable improvement in oral health of children in the UK over the last forty years, a significant burden of dental caries remains prevalent in some groups of children, indicating the need for more effective oral health promotion intervention (OHPI) strategies in this population. ***Objective****:* To explore the implementation process of a community-based OHPI, in the North East of England, using Normalisation Process Theory (NPT) to provide insights on how effectiveness could be maximised. ***Methods:*** Utilising a generic qualitative research approach, 19 participants were recruited into the study. In-depth interviews were conducted with relevant National Health Service (NHS) staff and primary school teachers while focus group discussions were conducted with reception teachers and teaching assistants. Analyses were conducted using thematic analysis with emergent themes mapped onto NPT constructs. ***Results:*** Participants highlighted the benefits of OHPI and the need for evidence in practice. However, implementation of 'best evidence' was hampered by lack of adequate synthesis of evidence from available clinical studies on effectiveness of OHPI as these generally have insufficient information on the dynamics of implementation and how effectiveness obtained in clinical studies could be achieved in 'real life'. This impacted on the decision-making process, levels of commitment, collaboration among OHP teams, resource allocation and evaluation of OHPI. ***Conclusions:*** A large gap exists between available research evidence and translation of evidence in OHPI in community settings. Effectiveness of OHPI requires not only an awareness of evidence of clinical effectiveness but also synthesised information about change mechanisms and implementation protocols.

Key words: *oral health, dental caries, evidence-based dentistry, normalisation process theory, health promotion, health plan implementation*

Introduction

Dental caries is a common, but preventable, disease in children and young people, affecting their quality of life (Plutzer and Spencer, 2008). However, it impacts hugely on National Health Service (NHS) resources, with dental caries being the most common reason why a child between the ages of 5-9 years is admitted to hospital in both England and Scotland, and these figures continue to rise, year on year (RCS England, 2015). Overall, dental treatments cost the NHS £3.4 billion per year for primary and secondary dental care services for both children and adults (PHE, 2014; Claxton et al., 2016), while the cost of hospital admissions for dental treatment involving general anaesthetics (GA) was £30 million in 2012-13 (DoH, 2013). Furthermore, repeat dental treatments under GA in some children have also been reported in some regions in England (Deery, 2015).

Arguably more important than the financial costs, these hospital admissions are associated with significant morbidity and are not without mortal risk and these children suffer pain, infection and experience effects on body weight, growth and quality of life (Deery 2015),

Despite the improvement reported with the recently released oral health survey findings of 5-year olds in England (PHE, 2016), the strength of correlation between dental caries prevalence and deprivation in 2008, 2012 and 2015 remained the same, suggesting similar and persistent inequalities in oral health.

There is a range of evidence of effective interventions from studies undertaken in clinical settings but uncertainty remains about their effectiveness when rolled out in 'real life' i.e. community settings (Moore, 2015) and according to Waters *et al.,* 2011, generally, a large gulf exists between available evidence and its implementation. To understand the process of effective implementation of interventions, it is important to identify, interpret and translate their components into daily routine practice (May *et al.*, 2009). A relatively recent review (Cooper *et al*., 2013), concluded that there was insufficient evidence for the efficacy of primary school-based behavioural interventions for reducing caries, and recommended a need for high quality research to utilise theory in designing and evaluating interventions to change oral health related behaviours in children. The current study investigated a supervised toothbrushing with fluoridated toothpastes (SVTB) scheme, which represented the most commonly implemented oral health promotion intervention(s) (OHPI(s) in nursery and primary schools in North East England. In Durham and Darlington, the SVTB scheme started in 2005 and covered the non-fluoridated areas of Chester-le-Street and Durham, Durham Dales, Easington, Sedgefield and Darlington. In Teesside, the SVTB scheme was introduced to primary schools in 2009 with approximately 100 settings (nurseries and schools) participating. In Newcastle, schools willing to take part in the SVTB scheme were supported by the then North East Primary Care Trusts (PCT) - however, there was

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no direct involvement of the PCT in the facilitation and delivery of the scheme. In Northumberland, North Tyneside, Sunderland and Gateshead, the scheme was neither supported nor delivered to schools in the areas. A case study (Tees daily supervised tooth brushing programme in schools), described in the document 'Local authorities improving oral health: commissioning better oral health for children and young people', indicated the positive impact of SVTB on reduction of dental caries in schools participating in the scheme compared with non-participant schools (PHE, 2014).

Using qualitative research methodology, the experiences and perceptions of individuals involved at both strategic and operational (delivery) levels of OHPIs can be explored. Normalisation Process Theory (NPT) is a recently developed middle range theory on implementation. It provides an explanatory framework to evaluate complex interventions (May and Finch, 2009) as it comprises factors that can be used to describe effectiveness in implementation i.e "routinisation" in practice. These include the social organisation of embedding, integrating and sustaining interventions that have been found to occur. Such omissions account for many well-evidenced public health interventions failing at implementation or failing to be sustained. NPT facilitates, understanding and identifying what people do and the purposive actions taken in investing resources to achieve defined goals (May *et al.*, 2009). Therefore, in order to provide some insights into maximising effectiveness of OHPIs, this study explored the implementation process of a community-based OHPI, in the North East of England, using Normalisation Process Theory (NPT).

Methods

A favourable ethical opinion was obtained from Teesside University, School of Health and Social Care Research Ethics and Governance Committee. Participants selected for the study were from the then North East Primary Care Trusts (PCT) and had knowledge and experience of delivering oral health promotion interventions, and specifically the SVTB scheme, to schools in the area. At the start of the study in 2010, there were children aged 2-4 years from 23 settings (schools/nurseries/children's centres) participating in the scheme in Durham and Darlington and from 100 settings in Teesside. The study was undertaken prior to the NHS reorganisation under the Health and Social Care Act of 2012, when commissioning for community dental health was the responsibility of the Primary Care Trust (PCTs) (now the responsibility of local authorities). Consequently, research and development managers in PCTs were approached for permission to interview NHS staff associated with the commissioning and delivery of OHPIs; specifically the "supervised toothbrushing with fluoridated toothpaste scheme" (SVTB) currently being delivered in schools in the area.

The staff involved with specific roles in: i) strategic planning, commissioning and decision-making (6 participants); ii) delivery of oral health promotion interventions (6 participants) and; iii) schools (teachers/ teaching assistants) delivering SVTB (7 participants), were contacted and provided with a Study Information Document and invited to take part. Valid written informed consent was obtained from participants recruited into the study.

One to one in-depth interviews and focus group discussions took place between December 2011 and August 2012. The interviews and focus group discussions were undertaken by the principal investigator (JO), a dentist who worked closely with a supervisory team comprising a paediatric dentist, a nutritionist and a professor in public health throughout the whole period of the research. Topic guides for the interviews and discussions were developed using the four main NPT constructs; coherence, cognitive participation, collective action and reflexive monitoring. The guides helped to explore the process of social organisation and dynamics that all those involved in the strategic and operational aspects of implementation of OHPIs need to recognise and embed in their practice. Interviews and focus groups were undertaken in batches and the interview guide was revised to include emerging issues as data collection progressed. Interviews and discussions were tape-recorded with participants' consent, and later transcribed for analysis.

Data analysis was undertaken as each batch of interviews was transcribed to identify areas that required further exploration in subsequent data collection. Data were exported into NVIVO 9 (QSR International, Cambridge, MA, USA) and assigned to a coding framework. Further data collection and analysis of proceeded iteratively until all data collected were coded and categorised. To ensure accurate analysis, each transcript was re-read and any new findings discussed with research team members.

Finally, selective coding was used to define any broader emergent themes, which were then mapped into the NPT framework, providing clear interpretation and linkage to the NPT constructs. Data were also examined for deviant cases and the confirmation of views across the range of participants assessed.

The trustworthiness of the study was enhanced by purposively selecting participants well placed to provide detailed information on the intervention. The participants were effectively engaged with throughout the data collection process.

Results

The four elements of NPT served as a useful guide to explore the social organisation and the interplay of factors associated with implementation process of the SVTB. Themes and subthemes mapped to the NPT constructs are outlined in Table 1.

A summary of findings is presented below while some quotes from participants are highlighted in Boxes 1 to 4. Participants' quotes are also indicated in the boxes; quotes from NHS staff are labelled as NHSS1, NHSS2, etc. while quotes from school staff are labelled as SS1, etc.

1. Coherence (Box 1)

Coherence relates to ensuring comprehension of the need for an intervention and its constituent parts amongst people involved in its implementation. It explores how well implementers correctly interpret the requirements to meet the objectives, and envisage reaping the potential benefits of the intervention (May *et al.*, 2009; 2010).

Table 1. Themes and subthemes mapped to the NPT constructs

NPT	*Themes*	*Subthemes*
Coherence	Understanding how to tackle the problem	- An understanding of poor oral health - Availability of robust evidence of effective OHPIs - Identifying and deciding on the appropriate OHPI to implement. - Determining requirements for demonstrating effectiveness of OHPIs
	Understanding the benefits of the OHPI	- Identification of the potential value and benefits of evidence-based OHPIs - Considering of the benefits in strategic planning and decision-making
	Understanding how to achieve the potential value of the OHPI	- Ensuring fidelity when implementing OHPI for maximum effect
Cognitive participation	Investment in ownership of the OHP intervention	- Endorsement of the OHPI - Engagement with the OHPI
	Investment in management structure	- Organisational and leadership structure
	Investment in participants' commitment	- Support and training
Collective action	Building relationships	- Communication and collaborative working - Relationship with school teachers - - Uncertainties about future of OHPIs - Lack of interest in OHPIs
Reflexive monitoring	Challenges in determining oral health improvements	- Impact of other oral health promotion activities - Insufficient funding to conduct full evaluation - Indicators used in assessing OHP improvement
	Process evaluation	- Lack of guidance - Feedback process
	Modification of intervention(s)	- Changes made

Most participants were aware of the relevance and importance of research evidence when considering which interventions to implement. They had positive perceptions of the use of evidence in decision-making and had used the evidence from systematic reviews on clinical effectiveness of interventions to help guide their decisions.

However, it appeared that a lack of detailed scrutiny and interpretation of evidence for OHPIs impacted on choice of interventions, as well as the commissioning and provision of a recurrent budget for oral health promotion. Interpretation and synthesis of evidence is essential when selecting an intervention, the requirements for adapting and tailoring it to the local setting, assessing potential barriers to implementation and monitoring the progress and suitability of the intervention (Armstrong *et al.*, 2011). Despite strong evidence for the effectiveness of an intervention, commissioning staff still struggled to establish it as a routine element of preventive dentistry with funding having to come from non-recurrent (rather than mainstream) budgets. Adequate synthesis of evidence was seen to be key in enabling efficient case-building to show relevance, priority and overall effectiveness of specific interventions and guide the decision-making process by PCT executives.

Understanding and ensuring fidelity in implementation is essential to ensure that similar levels of effectiveness as obtained from research evidence are attained when IHPIs are implemented in the "real world". Inconsistency in the mode of delivery of the SVTB was evident in some schools. Oral health promoters described efforts to make the intervention an easier task for the supervising staff in schools by introducing some flexibility into the toothbrushing. For example, allowing it to take place anytime during the day, for as long as the teachers wished and also allowing interruption and re-initiation of the scheme. There appears to be a need to establish the importance of fidelity to protocol when evidence-based OHPIs are being implemented.

2. Cognitive participation (Box 2)

Cognitive participation describes the relationship between those involved in implementing an intervention. It indicates the need for implementers to work together, decide on the procedures, and engage with the implementation process. It also helps understand how they invest commitment and ownership towards the intervention (May and Finch, 2009).

Cognitive participation requires endorsement, engagement and continuous commitment to (or "buying into"). Endorsement involves the decision-making and agreement by all participants to deliver it. In the implementation of the SVTB, endorsement lay primarily with the strategic decision-makers i.e. the directors, consultants or dental public health advisers, in most areas. In one area, endorsement was missing because there was no consultant/adviser; the oral health promotion team was keen to contribute, but felt that their expertise and capabilities needed to be recognised to allow OHPI to progress more smoothly.

Engagement requires a genuine commitment to involve all people effectively at various stages through partnership and empowerment. As much as partnership in the team is crucial, from the data collected, in some instances it appeared to be rather weak. An essential aspect of partnership and empowerment is communication and interaction, which relies on strong managerial support. Some of the oral health promotion coordinators felt that they would benefit from stronger communication with some senior team members and more support from them in engaging with the schools.

Continuous investment in the commitment of those individuals implementing the OHPI through formal and informal acts of support for all taking part, appeared to be crucial, especially in areas where there was no, or limited, involvement of directors or consultants. In other areas, the wider availability of consultants and dental advisers had a positive influence on implementation, especially in providing some direction over choice of intervention and how to implement. Effective leadership provides clear roles, effective teamwork, effective organisational structures, as well as appropriate staff involvement in decision-making (McCormack *et al.*, 2002), which can have a substantial impact on the intervention's sustainability. In some areas, business managers had been introduced to manage the work of some of the oral health promotion coordinators. Some of the staff felt that this reinforced a weakness in investment in ownership and commitment and would have preferred direct supervision from consultants to address some of the communication gaps identified between the oral health promoters (OHPs), and consultants/directors.

3. Collective Action (Box 3)

Collective action sheds light on the interaction between implementers, their efforts at obtaining knowledge and in maintaining confidence in their activities. This construct helps to identify all the operational aspects of delivery of an intervention, allocation of tasks and how the tasks are undertaken.

The OHPs were largely responsible for the operational aspects of OHPI implementation. Most participants perceived the need to develop and maintain strong collaborative links between all those involved in the SVTB implementation and in delivery of OHPIs generally. A recurrent theme in all areas was communication gaps and lack of cohesive working between senior and more junior members of oral health promotion teams, plus limited involvement of some senior members of the team. These factors can impact on building sustainable relationships and how participants (especially those operationally involved) perform the tasks and roles required of them.

In facilitating delivery, OHP staff contacted the schools, developed relationships with teachers and provided training and support for them, especially at the initial stages, before leaving them to deliver the intervention. Development of rapport with head teachers was seen as an important introductory aspect and key to sustaining the intervention, while some participants believed that it was important to build relationships with the whole staff, especially class teachers, to get the intervention working effectively. Other educational opportunities such as open evenings, and family-learning groups in schools were utilised to reach children and their parents.

The process of embedding an intervention depends on creating confidence in it and maintaining of trust in the expertise of those involved. With the changes in activities and work plans of OHP staff along with the major restructuring being planned in the NHS during data collection, there was some speculations over the future of OHPIs. There were also concerns about the roles and the services that would be offered once Clinical Commissioning Groups took over and much uncertainty about the future, including possible risks to continued delivery of the SVTB schemes because of shortage of funds.

Collective action requires that those involved in delivery build relationships enabling them to perform tasks as expected of them, especially where translation of evidence is required so that guidelines, policies and procedures are correctly followed. In addition, staff need confidence in the interventions and in their own skills and competence, while being adequately supported by their organisations (Murray *et al*., 2010).

4. Reflexive Monitoring (Box 4)

The reflexive monitoring aspect of NPT helps explain how implementers assess the impact of an intervention, identifying its worth individually and collectively using formal and informal avenues.

Assessing the effectiveness of OHPIs is needed to develop more effective interventions, disseminate good practice and make best use of resources. Useful feedback can also inform new policies development and their implementation (Petersen and Kwan, 2004). Most participants revealed challenges in determining OHPI's effectiveness generally and especially with the SVTB scheme.

In assessing how the effectiveness of the SVTB scheme was being determined, the pre- and post- interventions indicators were explored. Many participants felt that these indicators would not provide suitable information on the implementation process or the effects being derived. Co-ordinating staff believed that in order to successfully determine the impact of the SVTB scheme, it should be continued for longer with relevant outcome measures. Although, the short-term duration of an OHPI such as the SVTB scheme, was perceived as quite easy and flexible, some participants believed that the contribution and effectiveness of an OHPI would not be evident with such short periods of implementation.

Some team members elaborated upon the need for comprehensive evaluation processes and systems. Although they believed that determining oral health improvements could be challenging, they mentioned that formal programmes with evidence of direct local impact were needed. Monitoring delivery of the intervention in line with protocol usually involved irregular visits by the advisers to participating schools. In most cases the toothbrushing process was not witnessed and, in some cases, only telephone calls were made to the schools. The benefit of having appropriate evidence of effectiveness of the SVTB and OHP interventions in general was recognised. Teachers commented on the unavailability of data to show the impact of their efforts in delivering the interventions in their schools.

Reflexive monitoring requires regular structured mechanisms to monitor the process and impact of interventions using various methods; for this, individual and collective appraisals are required.

Discussion

In this study, elements of NPT helped to understand the implementation of OHPIs and oral hygiene practices in daily routine practice. NPT provided an insight and approach to systematically identify the various aspects to be explored in the implementation. The NPT tools were useful in assessing the dynamic and interactive processes between OHP team members, what guides decision-making, how they enact practice, the organisation they work in and how they appraise the delivery of OHP, both individually and collectively. NPT was a suitable choice for an assessment tool in the study, as the framework it provided was directed at whether this OHPI was fully embedded and integrated to achieve sustainable implementation processes for improved oral health. This required a comprehensive and rigorous understanding of the social processes and aspects of implementation right from its commencement into practice.

Evidence within the coherence domain indicated that there has to be adequate support for participation and action to achieve a successful outcome, as previous studies that used NPT in their research have found (Bamford *et al.*, 2012; Pope *et al.*, 2013). Those involved in delivery need to understand how the intervention works (and why), and their specific role in it. In the SVTB scheme, this varied across the groups of implementers. This finding is similar to those of Trubey and Chestnutt, (2013) who used Q-sort methodology to assess views of staff involved in the implementing of an SVTB programme and their need for training on the rationale the interventions. The participation of implementers should be based on a wider understanding of the evidence for the intervention. This is important in decision-making; identifying the right approach or strategy and developing evidence-based service level agreements for implementing, which are all crucial for a successful outcome. These findings concur with the World Health Organization's report on oral health (Petersen, 2003) that stressed the need for effectiveness of OHPIs. Public health commissioners and decision-makers require appropriate tools, capacity and information to choose appropriate intervention strategies and design policy options appropriate to their local circumstances in order to improve the performance of the oral health system (Petersen, 2003).

The use of a range of interactive activities to foster knowledge translation (KT) is currently advocated to increase the application of research and evidence-based knowledge (Schreiber and Dole 2012). These activities can enhance cognitive participation and enable the use of evidence, not just in the implementation itself, but also in developing a true sense of ownership and commitment to the intervention.

The study reiterated the need for greater partnership and cohesive working among implementers at all levels and this highlights a persistent isolated, compartmentalised and individualistically-focused approach that appears to operate widely- a situation which will never effectively promote oral health (Sheiham and Watt, 2000). The idea of partnership working flows into all areas of health promotion. It is only through this type of approach that those who are implementing health interventions will be fully enabled to contribute their expertise and resources to improve oral health.

Effective leadership policy and procedure in OHP is another area for development. By empowering OHP team members, the success rate of OHPIs implementation strategies, research utilisation and patient care will improve. Most importantly, OHPI leaders need to be appointed with a specific role to direct, manage and monitor progress efficiently, as recommended by the World Health Organization (Petersen, 2008). This OHP leadership role involves setting a clear vision for the future and driving sustainable change by working with, and empowering, the people involved (Meese, 2010).

It is crucial that in evaluating evidence for an intervention, the criteria employed are those that can determine whether the measured outcomes fully encompass the interests of people involved in decision-making, delivery and particularly those in receipt of the intervention. Stakeholders should agree the types of evidence that would be adequate in determining value (Lomas, 1997). Secondly, evaluation criteria should determine unanticipated as well as anticipated effects of the intervention, including benefits and failures (Hawe, 1994).

This study investigated strategic and operational aspects of the implementation of a commonly used OHPI; SVTB. Relevant participants in the NHS and in schools delivering the intervention contributed to understanding the gaps in implementation. The research was, however, conducted in the North East of England and the findings might, in some cases, be particular to the process of implementation in this area. It would be useful to compare implementation of evidence-based OHPI in different parts of England. Another limitation was inability to recruit participants from schools that declined or withdrew from participating in the SVTB. Moreover, the study did not investigate how leadership and management structures are developed for implementation of OHPIs and how these might be affected with the changes taking place in the NHS at the time the interviews were undertaken. Finally, some challenges were faced during data analysis and mapping to the NPT constructs. One limitations in using the theory was the overlap between the constructs, especially cognitive participation and collective action. The problem was overcome by ensuring that data were assigned to the construct that was most closely related to the specific context from which data were derived.

In conclusion, to increase the effectiveness of OHPIs, the use of NPT has helped to identify the following recommendations for their implementation (Figure 1). The key points for oral health promotion strategy makers and commissioners to consider are to:

- Revisit the "sense-making" aspect of evidence implementation;
- Reflect on the need to invest in all members of the team and encourage the 'ownership' of interventions being implemented;
- Review existing leadership and management structures, and;
- Re-examine and amend the processes by which OHPIs are monitored and reported.

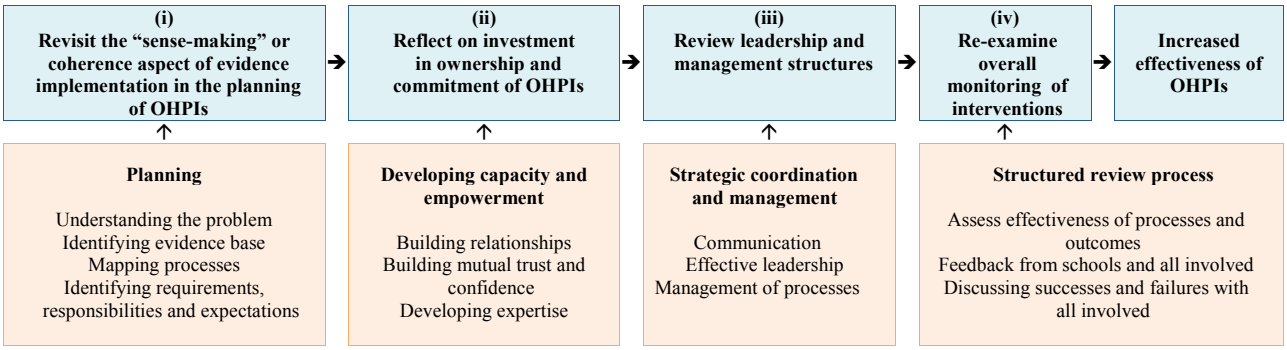

Figure 1. Recommended areas of activity to increase effectiveness in the implementation of OHPIs

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