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# Context and the evidence-based paradigm: The potential for participatory research and systems thinking in oral health

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## Abstract

The implementation of research evidence to promote oral health is critical, given the intransigent and emerging challenges for policymakers at a population level. Despite this, little attention has been paid to implementation research within the evidence-based paradigm. This is important as getting research evidence into clinical practice is not a linear path that consists of simple sequential steps. In this article, we argue that we need to consider a broader range of conceptual and methodological approaches to increase the value of information generated. This should be undertaken either in parallel with empirical and experimental designs, or in some cases, instead of. This is important if we are going to understand the complexity and contextual knowledge of the 'system', within which interventions are implemented. Involving key stakeholders alongside empirical and experimental designs is one helpful approach. Examples of these approaches include Patient and Public Involvement and the development of Core Outcome Sets, where the views of those that will be potentially affected by the research, are included. The use of theoretical frameworks and process evaluations alongside trials are also important, if they are fully integrated into the approach taken to address the research question. A more radical approach is using participatory designs and 'systems thinking'. Participatory approaches include subject matter 'experts by experience'. These include patients, their families, carers, healthcare professionals, services managers, policymakers, commissioners and researchers. Participatory approaches raise important questions about who facilitates the process, when it should happen and how the diverse actors become meaningfully engaged so that their involvement is active, democratic and ongoing. We argue that the issues of control, power and language are central to this and represent a paradigmatic shift to conventional approaches. Systems thinking captures the idea that public health problems commonly involve multiple interdependent and interconnected factors, which interact with each other dynamically. This approach challenges the simplicity of the hierarchy of evidence and linear sequential logic, when it does not account for context. In contrast, systems thinking accepts complexity *de novo* and emphasizes the need to understand the whole system rather than its individual component parts. We conclude with the idea that participatory and systems thinking

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help to unpack the diverse agents that are often involved in the generation and translation of evidence into clinical dental practice. It moves our conception of research away from a simple exchange between 'knowledge producers' and 'knowledge users' and raises both methodological and epistemological challenges.

#### KEYWORDS

complexity, evidence-based paradigm, implementation science, participatory research, systems science

## 1 | INTRODUCTION

The main aim of any public-funded health system is to improve health and well-being at both an individual and a population level, within a defined and constrained budget. As a result, the generation and implementation of health policies that are based on the best form of evidence is considered to be an important corollary.<sup>1</sup> In this paper, the evidence-based paradigm will be briefly reviewed, before examining the limitation of some of the inherent assumptions therein, particularly in relation to the importance of context. Given that many of the challenges facing dental public health appear to be relatively intransigent (eg dental caries in young children and the emerging concern about managing the oral health of dependent older people), we explore the contribution that participatory research can make towards understanding contextual knowledge, before looking in depth at the potential of 'systems thinking'.

## 2 | THE EVIDENCE-BASED PARADIGM

As Braithwaite et al<sup>2</sup> argued, the idea that the implementation of research evidence into clinical practice is a linear path consisting of sequential steps is simplistic at best. The 'translation chasms' from basic science—to applied health research—to evidence use in the clinic, are not always possible to be bridged.<sup>2</sup> There are many reasons for this, which will be explored in this paper. We argue that a broader range of conceptual and methodological approaches are needed, in order to make a meaningful contribution to understanding the complex problems commonly faced by dental policymakers and researchers. We also argue that understanding contextual knowledge of the 'system', within which the interventions are introduced, is key.<sup>1,3</sup>

To this end, we have seen the welcome addition of qualitative methods alongside randomized controlled trials. Qualitative approaches use semi-structured interviews or focus groups that ask participants and other important stakeholders in the research process, their view of the intervention and the context within which the intervention is located.<sup>4</sup> These are often described as process evaluations, which seek to explore the following key areas in empirical designs:

1. Intervention fidelity
2. Contextual factors that shape interventions and their implementation

3. Mechanisms that sustain or potentiate effects; and
4. Unexpected pathways and consequences.<sup>5</sup>

Despite this helpful development, a recent analysis showed that only 13% of trials exploring health interventions used parallel qualitative methods as part of the design of the study.<sup>6</sup> The authors found that very rarely did the protocols provide any substantive detail on the methods and how the qualitative work would inform the trial findings. Such approaches can provide great benefits to trials. However, these advantages will not be fully realized until they are embedded from both a methodological and epistemological perspective, rather than being conceived as a simple 'add-on' to existing empirical or experimental design. One recent example of the value of qualitative methods alongside trials in dentistry is the NIC-PIP trial, which explored the potential of a practice-based caries prevention programme.<sup>7</sup> In this study, the parallel qualitative study added real value and helped the researchers to understand the factors that sustained and/or moderated the effects of the complex intervention in NHS practices.<sup>8</sup> It also helped them to provide a meaningful interpretation of the results of the trial for dental policymakers. If we are to increase the value of information that trials provide, we need to ensure that the incorporation of qualitative methods undertaken in parallel, forms part of a gold standard, with the registered trial protocol specifying how and in what way qualitative methods will contribute to understanding contextual knowledge and how the 'system' operates. An example here might be the establishment of a process evaluation oversight committee with all key stakeholders, including service users, those working 'at the coal-face' (clinicians) and those who have influence at the macro-level of the system (policymakers and commissioners).<sup>9</sup> The role of the oversight committee would be to scrutinize both the trial and the process evaluation and reflect on the implementation of the findings and the 'pathway to impact' into day-to-day dental practice and/or policy-level interventions.

Another key area that can help ensure that end-users' perspectives and contextual knowledge are explicitly incorporated into trials of complex interventions is the development of Core Outcome Sets (COS). COS are a minimum set of outcomes that are collected in a trial for any given health condition. COS are consensus-based and as stated by Williamson et al,<sup>10</sup> 'have the potential to reduce waste in research by improving the consistency of outcomes measured in trials'. This is achieved by different

consensus methods including qualitative research with clinicians and patients, group discussions (eg nominal group technique), and structured surveys (eg Delphi technique). As Kirkham highlights, there is 'growing recognition that insufficient attention has been paid to the outcomes measured in clinical trials, which need to be relevant to health service users and other people making choices about health care *if the findings of research are to influence practice*'.<sup>11</sup> These approaches are starting to be used in dental public health, for example, in the emerging challenge of maintaining the oral health of older people as they lose their independence.<sup>12</sup> Here, researchers are working with older people to explicitly incorporate their views and understand what outcome measures are meaningful to them (DECADE: DEvelopment of a Core outcome set for orAl health services research involving DEpendent older adults). Incorporating these measures into future trials in this area have the potential to capture meaningful change and contextual knowledge in this population group.

Both of the initiatives discussed above highlight the increasing importance of involving key stakeholders in trials of complex interventions. Patient and Public Involvement (PPI) is one area that funding panels are also taking more seriously. However, until recently, there has been a level of tokenism among some researchers in their approaches to PPI. In one study, over two-thirds of applications for research funding (69%) did not contain any specific detail of how patients and the public were to be meaningfully involved, reflecting a lack of understanding about the importance of PPI.<sup>13,14</sup> Published guidance for PPI in the literature is developing, along with consensus principles<sup>15</sup> and highlights the challenge for researchers to ensure epistemic and ontological justice; that is, distributing power across all relevant stakeholders and ensuring their contextual knowledge and experience is privileged in the research process.<sup>16</sup> All too often, patients get allocated roles that lie at the periphery of the study process, with little influence on how the research is framed or conducted.<sup>17</sup> The incorporation of one or two PPI members on a research team does not always provide sufficient knowledge of the 'system'. Indeed, recent work in the PPI field related to cancer studies has shown that the voices of patients needed to be translated into systemic language in order for it to have an impact, and there is a need to better understand the context within which 'expert' and lay people were conversing.<sup>17</sup> Equally, 'the idea that users and producers of evidence occupy two separate worlds has not been helpful in accelerating progress with the evidence-based practice agenda'.<sup>1</sup> We need to shift our thinking away from seeing implementation as a 'service problem', once the evidence has been generated. In addition to PPI, the importance of involving those working 'at the coal-face' and at the macro-level of the 'system' during trial development is key. Implementation research suggests that there is much more promise in approaches that are interactive and tailored and where human agency is utilized.<sup>18-21</sup> In this context, it is not hard to understand the promise offered by participatory research, where the views of all key stakeholders in the 'system' are explored.<sup>22</sup>

### 3 | PARTICIPATORY RESEARCH

Participatory research seeks to incorporate stakeholder views to build contextual knowledge and include a broad range of study designs including participatory research and design, co-creation, co-design, co-production, action research and Mode 2 research. This is research that, in some way shape or form, embraces context and involves a broader range of perspectives in transdisciplinary models (for a detailed description, see Langley et al).<sup>23</sup> However, we must be clear here that this broad family of approaches should not be confused with PPI. People that sit on advisory panels or steering groups are a valuable form of patient involvement. However, they are not, in our definition of participatory research, sufficiently engaged in the research process. Within this paper, we will refer to 'participatory research' as a broad encompassing term for co-creation, co-production, co-design applied to research and one that involves all the key stakeholders, not just patients or service users. These approaches can be traced to a rich and diverse heritage from a range of academic disciplines including participatory action research, collaborative design, computer science and business studies.<sup>24</sup> They all have two primary drivers: democracy and pragmatism. They are democratic in that they work to the maxim that 'nothing should be done to me without my say'; pragmatic in the manner that they seek to reconcile differences between theory and practice (see Table 1). The pragmatic dimension is strongly tied to the wider appreciation of what 'evidence' is and which 'evidence' matters. The PARIHS framework, for example, highlights that for a healthcare intervention to be optimally implementable, 'evidence' cannot be purely based on research. It must incorporate experiential knowledge of healthcare professionals and patients, as well as including contextual evidence.<sup>25</sup> The ways in which these different strands of evidence are woven into an intervention design currently remains an under-studied area.<sup>26</sup> Yet, there is a general appreciation from implementation science literature, that it cannot be a simple additive process conducted by researchers, privileging evidence from some sources over others. Participatory approaches address both drivers by including subject matter 'experts by experience', such as patients, their families, carers, healthcare professionals, services managers, policymakers and commissioners.<sup>1</sup> They also include researchers with their research evidence.

Nevertheless, there are structural and systemic hierarchies that have to be addressed to enable these 'experts by experience' to participate in the research process. With this in mind, there remains three vitally important and as yet under-studied questions relating to all forms of participatory research:

1. Who facilitates the participatory process?
2. When should participation in the process happen?
3. How do these diverse actors become meaningfully engaged in such participatory research processes to ensure that their involvement is active, democratic and ongoing?

**TABLE 1** Differences between the evidence-based and co-production paradigms

Domains	Evidence-based paradigm	Co-production and co-design paradigm
Approach to knowledge	Knowledge has a hierarchical structure	Knowledge has a flat structure
Approach to evidence	Quality of evidence is largely dependent on one of 45 hierarchies of knowledge	Quality of evidence is weighed upon a case by case basis and is taken from the most relevant, appropriate, available and accessible sources. It is taken with critical scrutiny of the sources and appropriateness of the methods used to derive it
Philosophical paradigm	Empirical and positivist (a 'truth', variable or mechanism can be uncovered and measured)	Relativist (a 'truth', variable or mechanism are relative to the individual and society)
Epistemological stance	Hypothetical-deductive	Inductive
Reasoning	Deductive reasoning	Abductive reasoning
Implementation pathway	Knowledge is created and passed between researchers to clinicians to be implemented	Knowledge is embodied as it is co-constructed and co-created and transferred across settings using human agency (eg human intermediaries and communities of practice)
Nature of intervention	Fixed at one point in time	Prototypes emerge iteratively
Indexicality	Uncovered 'truths' at one point in time are relevant for future points in time	'Truths' are relative to one point in time
Context	Mechanisms of action are consistent across different contexts	Mechanisms of action are dependent on the context
Reflexivity	Researchers are separate to the experience of research	Researchers are 'within' the experience of research
Tacit knowledge	Ignored	Revealed during the co-production process
Unit of measurement	Point estimate of a population	Individual patient or person
Medium of expression	Written word	Engages senses 'meaning is making' [eg visual (art and design—objects as agents for change)]
Audience	Limited to those that understand 'science' speak (potential for 'epistemological injustice')	Inclusive

Note: We need to consider changing our approach so that knowledge is no longer simply an object, but something that becomes experienced, embodied, lived and actioned (eg human intermediary), so that it creates a sustainable evidence ecosystem and becomes transferred by human agency within a complex health system.

Central to all of these issues is control, power and language. As highlighted in the previous section, the predominant and prevailing model used in healthcare are that the academic research community controls the research process, who is involved, how they are involved and when. To move this to a participatory paradigm, the academic community needs to surrender some of the control and power, along with the language that is used to underpin and maintain these barriers, in order to create the conditions that enable genuine participation from nonacademic participants. The format of this participation is also critical. The dominance of the written word can be traced back to Plato and to Descartes and has been continued by an academic culture that seeks to promote abstract thought and cognition as a purely intra-mental activity, where written and spoken language is the main tool of thought and mode of explanation.<sup>27</sup> This can become a barrier to participation.

The fragmentation of academic disciplines into ever smaller silos of knowledge, each with its own language, terminology and shorthand, reduces the ability for communication across these boundaries and reduces accessibility for nonacademics.<sup>28</sup> At its worse, it can exclude and prevent participation by the public. As a result, there is

a need to find a common 'language' that can cut across these silos and connect people, in order for them to participate in a common research endeavour in a real and meaningful manner.<sup>29,30</sup> This goes beyond the mere translation into, and use of 'plain English'.

We argue that the practice of 'design' offers one structured and solution-focused process that is independent of spoken or written language and the control and power that this limited form of communication can often maintain. Over the past 10-20 years, the discipline of design has stepped beyond the limits of product, graphic and fashion and opened into new domains such as service design. Now widely applied in the financial, healthcare, leisure and other service sectors as well as to local and central government services across the world, service design highlights the capacity for design practises to be applied to 'products' beyond the physical, visual and tangible.<sup>31</sup> It takes abstract concepts such as service experiences, identifies practical and information needs of services and marries them up with the infrastructure, logistics, organizational structures and 'touch points' or 'interaction points' of service providers. Throughout the processes of doing this, designers use visual means of collecting and representing data about needs, ideas and solutions. 'Design' has the

potential to be emancipatory, enabling stakeholders to share tacit knowledge and communicate in a meaningful way that is not constrained by language.<sup>32</sup> In contrast, within their own domain, designers and engineers communicate through drawings, sketches and mock-ups or prototypes. In their own domain of practice, these can be highly technical and, to many, impenetrable. But the principals are transferrable without the technical information. Indeed, within their own domain of practice, these drawings and mock-ups typically contain multiple layers of different information relevant to different audience; less technical and more value-orientated information for conversations with the 'client', production technical for conversations with the manufacturers or more strength and integrity orientated for conversations with the engineers.<sup>33</sup> But while the layers of information change depending on who is in the conversation, the underpinning visual representation remains the same. Moreover, because these drawings are developed through interactions, they not only serve as a development process (and record thereof) but as a way of organizing the design to production process; these drawings structure the work process and the product. Rather than controlling the ability to communicate through a technical language that is only understood by those in a specific discipline, these modes of sharing can act as boundary objects and have a transcendental quality.<sup>34</sup> This is highlighted in the work of Nick Sousanis, where his ground-breaking PhD thesis 'Unflattening' used a comic strip medium to present an alternative way of 'seeing' and disseminating his research.<sup>35</sup> 'Unflattening' demonstrates the potential of combining text and images in order to extend the ability of the thesis to communicate meaning and expression. But it also highlights another component of 'Design': that of 'making' something that extends beyond mere cognition. This aligns with the work of McNiff, who talks about art as a form of communication and expression, but also, as a way of exploring and interpreting experience through making.<sup>36</sup> This moves communication beyond the limitations of language to a broader medium, exploring tacit thought through metaphor, symbolism and imagination and something that can represent often conflicting feelings and emotions. The activity of making something facilitates reflexivity,<sup>37,38</sup> as well as inviting multiple forms of knowing,<sup>39</sup> thereby extending the epistemological basis of our enquiry.<sup>40</sup>

Introducing these forms of thinking and communicating into a participatory research process produces a number of benefits; it can create a common language to catalyse different modes of thought, while ensuring that different perspectives are appreciated and empowered.<sup>41</sup> To be done properly, these creative, arts based workshop processes (as distinct from workshop processes that preference spoken and written language as the sole or dominant forms of thinking and expression) require facilitation, ideally by someone trained in creative arts or design-based disciplines and who is familiar with the academic world.<sup>42</sup> It also requires the researchers to take the position of a 'participant' in the process alongside patients and healthcare professionals, as opposed to leading the process, thereby further re-distributing power.<sup>43</sup> Distinct from designers, design researchers are university academics from a design discipline, who use the practices of 'design' as research methods. Design researchers

apply such practices to the exploration of a wide range of issues and have demonstrated that, in participatory research endeavours, there are particularly powerful ways of engaging other people in their research. Beyond exploring and examining experience, these creative approaches can be applied to analysing and interpreting data, participatory theory building, need identification and prioritization and many more 'technical' research activities.<sup>44</sup> This offers the potential of moving our research process far beyond our current approach and ensures tacit and contextual knowledge are accounted for.<sup>45</sup> In turn, this offers an approach that spans the conventional boundary between research and clinical practice.<sup>45</sup> We argue that this offers more potential for implementation.

Two examples of this approach from an oral health services research perspective are the development of a STroke friendly Oral health Promoting (STOP) toolkit using Experience-Based Co-Design (EBCD) and the development of resources to help residential care homes manage the oral health of dependent older people.<sup>46,47</sup> In the first example, we brought evidence-users together (stroke sufferers, their carers, clinicians and commissioners) in four stages to develop the toolkit. The facilitators of the EBCD collated the expressed needs of stroke patients using both audio-recordings and videos. These were represented on wall charts, flip-charts and 'trigger films' to co-create, in real time, a thematically organized map of the group's thoughts, including important areas to aid in the development of the toolkit. These informed the toolkit's content (eg education, information provision, sign-posting) and its format (design, layout, accessibility and availability), which were designed using APEASE criteria (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side effects/safety and Equity).<sup>48</sup> In the second example, we used a more 'designerly' co-design process, led by design researchers, with care home managers, carers and residents to create a series of resources derived from the NICE guidelines NG48.<sup>49</sup> These are now being tested in a feasibility study with a parallel process evaluation to assess the fidelity and potential effectiveness of the intervention, with a focus on factors that sustain and/or moderate the effects of the complex intervention in practice, using an overarching theoretical framework.<sup>36</sup>

Co-design has also been applied to a dental strategy for improving the quality of education for Dental Care Professionals in Wales and ensuring the future dental workforce for this group are fit for purpose and address future population health need. Here, groups of stakeholders, with contrasting views, were brought together to co-produce a workforce strategy. Over three time points, creative co-design workshops were held to understand future oral health need in Wales, the Dental Care Professional workforce needed to address this need and identify the training required.<sup>50</sup>

## 4 | COMPLEX SYSTEMS

As we have outlined above, many of the complex [dental] public health problems we face today involve multiple interconnected factors none of which occur in a vacuum. Such complex problems

involve heterogeneous, interdependent influencers, which interact with each other in complex and dynamic systems. This stands in contrast to many of the approaches that are traditionally employed in empirical designs. As highlighted in our earlier paper,<sup>1</sup> 'trialists routinely pretend that uncertainty does not exist. A single point estimate is chosen for all these parameters, a design created that would work well if all of those guesses happen to be true simultaneously (an unlikely event) and then that design is put into a grant that they hope gets funded'.<sup>51</sup>

Systems thinking takes a different approach and essentially accepts complexity *de novo* and emphasizes an understanding of the whole system rather than the individual components.<sup>52,53</sup> It is a 'collective of analytical approaches that share in common the capacity to examine the big picture, that is, a problem and the context in which it is embedded'.<sup>36</sup> As such, it is the opposite of the traditional cause-and-effect or linear sequential logic that can pervade the traditional evidence-based paradigm (see Table 1). Instead, it argues that factors in any 'system' work interdependently and cannot be 'controlled for' or simply treated as 'confounders'.<sup>54</sup> As such, it sees the 'system' as a complex adaptive process, which can interact in dynamic, idiosyncratic, unpredictable and nonlinear ways. We would argue that dentistry is one such 'system'.

Systems thinking has been recognized for four decades,<sup>55</sup> but has only relatively recently begun to be applied in clinical practice. It has been applied to public health,<sup>56</sup> intervention development and evaluation,<sup>4</sup> and implementation science,<sup>2</sup> and there are some limited examples in guideline development.<sup>57-59</sup> To date, the application of systems thinking to public health has taken many different forms from complex interventions, to interventions as 'events' within complex systems.<sup>60,61</sup> A current and dentally relevant example are the use of systems thinking to evaluate the health impacts of a soft drinks industry levy for the Treasury in the United Kingdom.<sup>62</sup> The soft drinks industry levy is highly context dependent and involves a range of stakeholders, including government, industry and consumers. It also has a host of potential impacts including effects on the media and the public discourse on sugar, consumer acceptability, reformulation and consumption, along with the health impacts, including obesity and dental caries. The evaluation considered all of these elements as part of a complex system.

A further example where value could have been added by systems thinking was in the FICTION trial.<sup>63</sup> This was a multicentre, three-arm parallel-group, participant-randomized controlled trial set in primary dental care in Scotland, England and Wales. Children aged between three and seven years of age, with at least one primary molar tooth with decay into dentine, were randomized into three arms: (a) conventional management with 'best-practice' prevention; (b) a biological approach that sealed in active decay using fissure sealants alongside 'best-practice' prevention; and (c) 'best-practice' prevention alone. 'Best-practice' prevention included dietary and toothbrushing advice, topical fluoride and fissure sealing of permanent teeth. There was no evidence of an overall difference between the three treatment approaches for the experience or episodes of dental pain or dental sepsis (or both) after a median follow-up time of 33.8 months.

The findings of this trial, on their own, are difficult to interpret. The study was based on a superiority design, so does not have the power to infer equivalence or noninferiority. Equally, 10% of participants had 'a major treatment deviation from their randomized treatment arm' which meant that there was a high number of participants who crossed over from one arm to another during the duration of the trial.<sup>63</sup> In similarity with the NIC-PIP trial, researchers undertook a parallel process evaluation, which used an underpinning theoretical framework ('practice theory').<sup>64</sup> This captured the experience of stakeholders at the micro-level, using interviews with child-parent dyads and dental professionals, revealing a number of factors that influence the management and prevention of dental caries in children. This could have been *further* augmented by systems thinking at a meso- and macro-level, to capture the views of dental commissioners, dental public health professionals and senior policymakers.

A complexity lens would include the likely negative impacts on dental businesses, on health equity, equality and explore impacts on dentistry economics. Systems thinking would not only explore the impact on individual patient's oral health, but also societal impacts: financial and economic costs, the feasibility and health system considerations, and implications for the dental workforce and profession. This is also articulated in the 'Evidence-to-Decision' example provided by Rehfuess et al.<sup>65</sup> This type of approach involves a shift away from thinking about a final or definitive snapshot at one point in time, but rather takes the view that the narrative continues and is ultimately inconcludable. Instead, systems thinking would provide an indication of the 'direction of travel' (benefits and/or harms) rather than a final verdict on effectiveness or success. As Rutter et al.<sup>56</sup> point out, the critical question is not: does the intervention fix a problem but rather, does it reshape the system in favourable ways?

This explicit recognition of the transitive nature of change is a critical element of systems thinking. As Egan et al,<sup>66</sup> outline in their two-part 'how to' guidance document, a systems approach can best be summarized as 'thinking about the bigger picture', and understanding how different agents (people, services and organizations) interconnect and influence one another and how this evolves and changes over time. The authors detail four different ways that researchers can take to a systems perspective: systems thinking, systems mapping, computation modelling and innovating new approaches. While systems thinking is often thought of applying to upstream interventions, such as the soft drinks industry levy or smoke-free legislation, it is also relevant to individual-level, family-level, community-level or primary dental healthcare team-level interventions. For example, in more downstream brief dental interventions (eg smoking or toothbrushing) the consultation itself can be seen as a micro-system, which is itself part of the broader healthcare system.<sup>43</sup>

Indeed, one could argue that an understanding of any interventional context implies the adoption of a complex systems perspective.<sup>67</sup> In one of the few examples to date, Orton et al<sup>68</sup> showed how a systems approach could be applied in practice in a community setting. The study was an evaluation of 'Big Local': a project that involved 150 disadvantaged areas in England, who had been given

£1M over ten years to develop their local community. The evaluation used ethnographic methods, a qualitative approach that helped capture the complexity and the emergent and nonlinear processes in the intervention. It also helped the researchers understand the interdependent relationships over time in diverse contextual spaces.

## 5 | DISCUSSION

Orton's study emphasizes the theme that has been developed though-out this paper, namely the importance of contextual knowledge, the methods that can be used to elucidate this and how these approaches should be considered alongside empirical designs, which form the basis of the evidence-based paradigm. We have highlighted the value of qualitative processes alongside empirical designs, consensually developed core outcome sets, participatory research and systems thinking. As Braithwaite et al<sup>2</sup> argue, there is a pressing need to bring together complexity and implementation science, incorporating such approaches as theoretically driven trials, step-wedge designs, realist process evaluations, stakeholder analysis, systems mapping and social network analysis. As highlighted above, the use of such methods helps unpack the diverse agents that are often involved in the translation of evidence into clinical dental practice: patients, dentists, dental managers, insurers, commissioners (who already exist in ecosystems at different localities).

There is also a more fundamental issue, which derives from the ontological basis of participatory research and complexity thinking. Namely, the challenge that there is a false separation between 'knowledge producers' and 'knowledge users' in the evidence-based paradigm. We argue in this paper that this conceptualization of knowledge 'flow' and the epistemic and ontological injustice that this can create is manifest at present. Instead, we argue that 'knowledge producers' and 'knowledge users' are interdependent and that understanding contextual knowledge is key in complex interventions that involve multiple stakeholders. If we are to move away from a simple and static linear model of knowledge generation and translation, we need to embrace complexity and empower the different stakeholders involved. As Braithwaite et al argue, 'we must grapple with the world we actually inhabit, not the one we wish we did'.

The value of information that is generated from the over-reliance on randomized controlled trials for complex interventions needs to be challenged. Used on their own, they represent a significant sum of money. In the United Kingdom, over £15M has been invested by the largest applied health research funder in the last five years, with each trial ranging from £1.1M to £3.0M. Many found no effect and given that most were based on a superiority design, this lack of effect does not allow the policymaker to infer equivalence across the arms of the trial (due to lack of power). As Petticrew argued over five years ago, the greatest challenges 'are not methodological, but epistemological [...] the point is that not every study should be a trial'.<sup>69</sup> As highlighted above, the success or failure of an intervention in dental public health cannot rest solely on a change in a single primary outcome measure. What evidence is it that policymakers need

in dentistry? Why is it needed? For what decisions? How will it be used? What is the end goal of dental public health and how does this relate to evidence-based paradigm? We need to begin to ask the right questions and use appropriate methods to address those questions; to use the findings to help inform decision making whether by individual practitioners or policymakers. When trials are considered to be the best option, we need to think carefully about the parallel studies that should run alongside trials to augment the value of information offered. The challenge rests with us.

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