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Opening the black box: A study of the process of NICE guidelines implementation

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ABSTRACT

Objectives: This study informs 'evidence-based' implementation by using an innovative methodology to provide further understanding of the implementation process in the English NHS using two distinctly different NICE clinical guidelines as exemplars.
Methods: The implementation process was tracked retrospectively and prospectively using a comparative case-study and longitudinal design. 74 unstructured interviews were carried out with 48 key informants (managers and clinicians) between 2007 and 2009.
Results: This study has shown that the NICE guidelines implementation process has both planned and emergent components, which was well illustrated by the use of the prospective longitudinal design in this study. The implementation process might be characterised as strategic and planned to begin with but became uncontrolled and subject to negotiation as it moved from the planning phase to adoption in everyday practice. The variations in the implementation process could be best accounted for in terms of differences in the structure and nature of the local organisational context. The latter pointed to the importance of managers as well as clinicians in decision-making about implementation.
Conclusion: While national priorities determine the context for implementation the shape of the process is influenced by the interactions between doctors and managers, which influence the way they respond to external policy initiatives such as NICE guidelines. NICE and other national health policy-makers need to recognise that the introduction of planned change 'initiatives' in clinical practice are subject to social and political influences at the micro level as well as the macro level.

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1. Introduction

Clinical guidelines can been defined as systematically designed statements that summarise the findings of research into best practice, in order to assist clinicians in deciding the most appropriate care for particular clinical conditions [1–4] in reducing variation in healthcare outcomes and costs [5,6] and ultimately, in improving the quality of patient care [7,8]. The use of clinical guidelines as a means of disseminating best practice is extensively recognised, and it has been suggested that they can influence practice if developed, disseminated and implemented appropriately [9]. Yet the uptake of guidelines into practice is low or uneven [10–18]. This unevenness in implementing guidelines highlights an ongoing concern that too much emphasis is given to the policy formulation in the abstract introduction of evidence based medicine and cost-effectiveness in healthcare at the expense of a concern for what happens afterwards.

The vast majority of empirical literature on clinical guidelines implementation has focussed on the identification of barriers to or facilitators of implementation. A large number of potential barriers have been identified operating

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at different levels, such as the level of the clinician, the level of the patient, the organisational context and system barriers at the national level, such as national priorities as well as vested interests which mitigate against change or favour it [19–22]. Recent primary-care research has suggested that the organisational factors identified in previous research as external 'barriers' were in fact emergent properties of the complex interactions between key stakeholders that together create the organisational context and its structure [23]. This suggests that inquiring into the context and process of implementation may offer a better understanding of the role of work place contextual factors in guidelines implementation.

This paper offers a process analysis of guidelines implementation as it unfolded across time. It aims to inform 'evidence-based' implementation by providing further understanding of the process of introducing and using scientific and technological developments in practice using NICE guidelines as exemplars. For the purpose of this research *implementation* is defined as a controlled activity aiming to introduce and encourage the uptake of a new policy or intervention that embodies pre-defined criteria (*e.g.* strong evidence of cost-effectiveness, priority areas and resources available) [24]. NICE guidelines were used as exemplars because their publication and recommendations are believed to be based on robust evidence of cost-effectiveness. However, like the evidence about clinical guidelines in general, there are marked variations in the uptake of NICE guidelines and although previous studies [11] have identified the obstacles to the implementation of NICE guidelines, they have only provided limited insights into the contextual circumstances that determine implementation success or failure.NICE was set up in 1999 by the Labour government to perform the function of rationing, to make recommendations for both the clinical effectiveness and the cost-efficiency of particular interventions, and to assist the drive for high-quality, cost-efficient care by producing clinical guidelines to be disseminated to front-line clinicians [25]. Developing a NICE clinical guideline takes 18–24 months from the time NICE is requested by the Department of Health to instigate a guideline to its publication date [26]. NICE commissions its National Collaborating Centres to develop its guideline. These Centres establish a Guideline Development Group which is comprised of mainly clinical experts, economists and policy-makers who review the evidence, undertake systematic reviews of the literature and develop the guidance. An independent Guideline Review Panel oversees the development of the guidelines and takes responsibility for monitoring adherence to NICE guideline protocol. In particular, the panel aims to ensure that stakeholder comments have been adequately considered and responded to. The panel includes members from the following disciplines and interests: primary care, secondary care, lay, public health, academia and industry.

However, it is not clear whether NICE guidelines represent a form of clinical governance and the extent to which health organisations are expected or required to implement them. For example, NICE itself has recommended that clinical guidelines should be disseminated to front-line clinicians in a manner that does not override clinical autonomy [27]. By contrast, according to the Department of Health [28], NICE guidelines are to be understood as top-down governance performance standards that are centrally prescribed and monitored.

Table 1
National agencies responsibility for monitoring adherence to NICE guidelines.

Department of Health
• Monitor healthcare organisations to check on implementation of each piece of NICE guidance
• The increasing distance of DoH from responsibility for clinical governance at the local level reduces their capacity to influence the process and supply valid information to the Department of Health.
The Commission for Health Improvement
• Examine systems for ensuring adherence in its inspections, but these are not frequent or detailed enough to give an adequate picture of progress

NHS organisations' adherence to NICE guidelines has historically been reviewed externally.

However, as Dent and Sadler [29] argue (see Table 1) responsibility for monitoring adherence is ambiguous, with several agencies potentially involved, but no clear lead role, and often no 'objective' indicators of what constitutes successful implementation are specified.

NICE appears to have recently changed its approach to implementation which suggests a recognition that providing rigorous evidence about the effectiveness, efficiency and safety of health care interventions and technologies is not sufficient to account for whether they are introduced into practice or not [19,29,30]. Their approach involves a more proactive process of transferring clinical guidelines to target audiences, supported with the production of tools to aid putting NICE guidelines into practice and policies that promote shared learning to raise awareness of how to implement NICE guidance, particularly in the context of general practice in the UK, where clinical autonomy has traditionally been strong. The study reported here tracked two distinctly different NICE guidelines [Obesity [31] and Chronic Heart Failure [CHF] guidelines [32] since their publication and explored how local healthcare providers and organisations respond to NICE clinical guidelines; the nature of the process by which clinical guidelines are implemented, examining how and why they were introduced, received and used by front-line providers.

2. Methods

2.1. Research design

Previous studies of the implementation process have studied the process retrospectively and focussed on isolated events or snapshots [11]. However it is argued that the implementation process is ideally explored through the use of a prospective, longitudinal design [33] from when guidelines are initially introduced into the local context to follow-up at different phases to shed some light on the nature and shape of the implementation process. Additionally, a study examining the implementation of NICE guidance has shown that simply relying on quantitative data regarding the use of drugs was insufficient to identify the uptake of guidelines, while the qualitative interviews

Table 2
Study design with number of informants interviewed at each phase.

Organisational context	Case-study 1		Case-study 2	
	Phase 1	Phase 2	Phase 1	Phase 2
PCTS	13 interviews (*n*: 13 informants)	9 interviews (*n*: 2 new informants)	12 interviews (*n*: 12 informants)	8 interviews (*n*: 2 new informants)
NHS hospital	11 interviews (*n*: 11 informants)	8 interviews (*n*: 1 new informant)	7 interviews (*n*: 7 informants)	6 interviews
Total	74 interviews/48 informants			

showed that although prescribing had increased the new patterns of prescribing were not necessarily in accordance with guidance [11].

Case studies can provide rich empirical data; enabling understanding of such complex phenomena as the implementation process [23] so this study adopted a comparative case-study design. In all, two case studies were explored involving primary and secondary care in Southern England. Both case studies involved one small to medium size Primary Care Trust[1] (PCT) and one hospital which served diverse urban populations.

Each case-study had two phases and was followed prospectively for a period of 6 months in order to understand how the implementation process unfolded. During the first phase of each case-study the implementation of the guidelines was explored retrospectively in a PCT (since the time of publication) followed by the Acute NHS Trust that was commissioned by the PCT to provide acute health services. The second phase of each case-study involved a second round of unstructured interviews with, where possible, the same key stakeholders in order to examine further developments and phases in the implementation process (Table 1).

Two distinctly different types of NICE guidelines were used as exemplars as previous studies [34–41] have suggested that the characteristics of the guideline influence the shape of the implementation process. These were a more recent one on Obesity and a more longest-standing one, on CHF. These represent two distinctly different types of guidelines: the recommendations in the Obesity guideline encompass system changes across healthcare, local authority and lifestyle-change; while the CHF guideline only involved changes to clinical services and practices. In the Obesity guideline for example NICE recommendations cover a broad area, including interventions for treatment, prevention and management of obesity; they cover system changes across healthcare, local authority and lifestyle-change and are presented over a number of distinct sets of clinical guidelines. In contrast, in the case of the CHF guideline, NICE recommendations cover the management of patients with CHF and so are focused on CHF treatment, specifying changes to clinical services and practices only, which are presented in a single clinical guideline.

[1] Primary Care Trusts (PCTs) were currently NHS organisation responsible for commissioning the best possible health care for everyone resident within their geographical boundaries and were created to integrate clinical and fiscal decision-making over a population of approximately 100,000–300,000.

2.2. Sampling

The snowballing technique (identification of further key informants during the fieldwork) was used to identify a sample of key informants involved in the implementation process for face-to-face informal interviews. Given that informants were recruited by acquaintance they were likely to tip off the researchers to potential informants in their own network, who were therefore likelier to share the same interests, values and beliefs. Hence, purposive snowball sampling was resorted-to to enhance the credibility of the findings and enable collection of data from informants more closely involved with the subject of research [42] and explore a range of different perspectives from those with diverse and sometimes competing interests. Finally, to assure that conceptual generalisations could be made, 'theoretical saturation', that point in the research process where new data or themes cease to emerge during coding [43], was relied-on to guide the decision that recruitment of new informants was complete in each case-study.

In total, 65 informants were invited to participate in the study and 48 informants were recruited which included 16 doctors, eight of which were General Practitioners [GPs] (of whom two had a special clinical interest in cardiology, one in obesity, four in practice base commissioning, and one in public health); and eight hospital consultants (four practicing solely in clinical settings, two cardiologists, one endocrinologist, one gastroenterologist, and four Trust professional executives with managerial duties); 11 senior and nine middle non-medical managers; 10 nurses; and two allied health professionals. Twenty-eight informants were interviewed twice and eighteen only once. Seven informants never responded and ten declined the invitation to participate in the project due to time limitations. In total 74 interviews were carried out over the two phases (Table 2).

2.3. Data collection and analysis

Data collection was carried out between September 2007 and March 2009. Before any fieldwork was carried out, all informants were provided with information sheets about the research project to develop an understanding of what was required from them and give informed consent. Loose topic interview guides were developed and derived from the theoretical and empirical literature.

During the first phase of interviewing three major themes were explored which were perceptions of the guidelines, their implementation and future operational plans for sustainable uptake. In the second phase of interviewing one of the key themes was to explore the

circumstances that may have influenced changes in operational plans for guidelines implementation.

All interviews were transcribed verbatim, transcripts were anonymised and a code number was assigned for identification purposes. Data analysis was conducted using an inductive, thematic approach and the constant comparative method. Data analysis was iterative and emerging themes were used to inform subsequent interviews. Newly gathered data were continually compared with previously collected data and its coding in order to refine the development of theoretical categories and explore new emerging ideas. An initial coding frame was developed to organise transcripts of the initial interviews and was then expanded and refined during review of transcripts from subsequent interviews. The coding process included adding and reconstructing codes as new concepts emerged and identifying new relationships between concepts. Atla.ti. software was employed for data handling.

3. Findings

This section presents data showing how local healthcare providers and organisations responded to NICE clinical guidelines; how the implementation process unfolded over a 6-month period across both case studies examining how they are introduced, received and used by front-line providers.

3.1. CHF guideline

The current official guidance suggests that Chronic Heart Failure (CHF) should be managed in clinics led by primary care professionals who should take the lead in the treatment of CHF patients in collaboration with hospital consultants (NICE 2003). All doctors were expected to adhere to clinical guidelines for heart failure (NICE 2003) that focus on the echocardiographic examination for assessing CHF patients and the use of drugs such as 'beta-blockers' that have been shown significantly to improve life expectancy. NICE revised and reissued these guideline in 2010 but this study did not explore whether the local implementation groups implemented this revision.

In the first case-study, seven informants out of the total sample of 23 were actively involved in trying to implement the CHF guideline, including one clinical leader (GP), one hospital consultant, two project managers, and three CHF nurses. In the second case-study, eight informants of 25 were actively involved, including one CHF nurse consultant, three CHF nurse specialist, two hospital consultants and two project managers. The remaining informants in both case studies consisted of managers with strategic rather than operational responsibility for the implementation of all NICE guidelines and clinicians, who may have put them in to practice.

The data from the first phase of both case studies suggested that the process started out controlled and staged. Forward planning was seen to be important for the implementation of the CHF guideline, including production of local guidelines and local dissemination plans. Developing a local plan was crucial for the teams responsible for the implementation of the CHF guideline, as it was the only way to attract the PCTs' financial support for implementation.

> Once it was agreed that CHF was a priority for the PCT, forward planning was important to develop action plans, local guidelines and dissemination plans. (CHF nurse-3, case-study/1)

> Shortly after the publication of the NICE guideline a service proposal was put together by the clinicians, with a bit of support from management, in order to comply with the NICE guideline. (CHF Nurse Consultant, case-study/2)

Existing clinical services and pathways of care for patients with CHF were subject to change in accordance with the CHF guideline in both case studies:

> We introduced a primary care clinic to get all the CHF referrals from the hospital and the GPs including a service for echocardiographic examination of CHF patients. (CHF nurse-1, case-study/1).

> We increased clinical skills and expertise in order to introduce the community service to meet the patients' needs. (CHF Nurse Consultant, case-study/2)

Around the same time the hospital's senior managers in the first case-study had also been keen to invest in CHF services in primary care, because this initiative was seen as an effective way to reduce high NHS *waiting times and meet Trust targets:*

> Our service was supported by the Hospital because their waiting list was so long. (CHF-1 nurse, case-study/1)

Similarly in the second case-study, lead cardiology consultants from the hospital supported the community specialist CHF service – in line with the CHF NICE guideline and the NSF – in order to transfer most of their CHF patients to the community specialist team. This was perceived as an opportunity to develop further the hospital cardiac department:

> The idea was that the cardiologists to offload the heart-failure patients to the community, and increase their scope to develop their particular area. (CHF Nurse Consultant, case-study/2)

Formal dissemination mechanisms were utilised in both case studies to increase GPs' awareness regarding the NICE guideline, including face-to-face meetings, educational and teaching workshops. The provision of financial incentives to GPs to change clinical practices was seen to be important because of the perceived complications involved in starting patients with new medications: for example, beta blockers for CHF patients, another key recommendation of the CHF guidelines. The PCT in the first case-study, however, did not support the local implementation team's request to provide financial incentives to GPs. This was felt to be the reason GPs' uptake of the guidelines was low.

> I still [January 2008] get referrals from GPs who are not on beta-blockers, and I suspect part of the issue is that beta-blockers are not part of the QOF framework, so there isn't that incentive to do it. If the PCT allowed us

to provide financial incentives I think we would be in a better place. (GP-1, case-study/1).

In contrast, in the second case-study senior managers allowed the introduction of financial incentives to encourage GPs' adherence to CHF guideline.

> It was great that senior managers supported us and allowed us to provide financial incentives through the *QOF* scheme. It was the biggest tool for GPs to act on the guideline, because they would get points for that. (CHF Nurse Consultant, case-study/2)

The receptive context for the implementation of the CHF NICE in the first case-study was not sustained in the long term. It was emphasised that managerial interpretations of adherence with the NICE guideline influenced the implementation process:

> I think that the PCT has successfully passed the national audit on CHF, and I think priorities changed and influenced implementation. It was perceived that the CHF service complied with the NICE guideline, which was enough for the PCT. (Project manager, case-study/1)

All three nurses involved in the implementation of the CHF guideline thought this influenced the receptiveness and motivation of 'key people' to engage in the implementation of NICE guidelines, and as such the CHF implementation team lost its status:

> I think the CHF team has lost it status. We had a lot of changes in our managers since we started, and also because the PCT's priorities have changed. Five years ago CHF was a huge priority. There was a huge amount of work done, but in the last couple of years the local group was dissolved, so the local GP is not as active. (Project manager, case-study/1)

One informant explained that once the clinical leader realised that scope and resources were no longer available to develop the community CHF service in accordance with his clinical interests, he deliberately disengaged from further efforts to sustain implementation of the NICE guideline:

> We used to have one GP, who was involved in the service and that is not the case anymore. He developed different priorities because he felt that he was not making the best use of his time. (CHF nurse-1, case-study/1)

This GP claimed changes in the PCT's priorities diminished his receptiveness to (and/or satisfaction with) being involved in the implementation of the CHF guideline:

> I used to make recommendations for changes. People seemed to take notice. But after a point I felt increasingly powerless, really, because we didn't have the commissioners on board with us from the PCT and secondary care. It was enough for them to comply with the basic recommendations of the NICE guideline. (GP-1, case-study/1)

The development of different priorities across collaborating organisations and the differently perceived success of the outcomes of implementing NICE guidelines have led to discontinuity of practices, and have influenced the shape of the implementation process. This is summarised succinctly in the following quotation:

> Since your last visit the local hospital's waiting times have been improved, so the GPs started to refer back to them and not to our service, which is in accordance with the NICE guidelines [. . .]. Our referrals were going down and the PCT asked us to review our service [. . .] And we struggle to get funds from the PCT to implement many of the things we initially agreed to do. There is a possibility that our service will not exist in six months time. (CHF nurse-1, case-study/1)

In contrast, in the second case-study the receptive context for the implementation of the CHF NICE guideline was sustained over the long term. However, despite the strong clinical leadership, there were instances when the informants involved in CHF guideline implementation felt that the process was uncontrolled in the sense that outcomes were unpredictable:

> We had good teamwork and good leaders and good support, many action plans and clear time scales, but when we were trying to implement them into reality, it was not like that. It is possible to be strategic. You know where you want to go, but it was not possible always to predict outcomes. So there was a bit of uncertainty there. (Operational manager, case-study/2)

A key issue raised by the three CHF nurses who were involved in the implementation of the CHF guideline in the first case-study was the uncontrolled aspect of the process across time, due to the local implementation team's inability to sustain the changes in clinical services and practices. It was felt that potential barriers to implementation of the CHF guidelines included the lack of clinical leadership across time and the temporariness of arrangements, particularly in the financial support received by the PCT:

> In the early stages of the process there was more control. We had our dissemination and training plans well organised. But I think when it goes further down it is diluted [. . .] but now the implementation team is disbanded, the GP is not leading the service anymore, and attention has moved away. (CHF nurse-2, case-study/1)

In contrast, the implementation of the CHF NICE guideline in the second case-study could be characterised as a process of mutual adaptation, where it was crucial to build upon a knowledge base shaped over time by the interaction between the initial objectives of the planning, the evaluation method used, and the new work routines. Informants explained that feedback was received about the impact of the process on the target population: the initial implementation strategy was revisited and revised in order to increase the uptake of stakeholders adopting the system:

> Following the audit results we went back to our strategies and tried to include new action plans, new routines that would improve the uptake of the guideline by our target group, and as the service evolved, our team became more confident and skills grew. (Cardiology consultant, case-study/2)

3.2. The obesity guideline

The following account of the implementation of the Obesity guidelines also shows that the implementation process varied markedly between the two case studies, suggesting that the organisational context maybe more important than the characteristics of the guidelines themselves.

The current official guidance is that obesity should be managed by multidisciplinary teams, involving professionals from primary and secondary care and the local authority. All GPs were expected to promptly measure all patients' body mass index while PCTs had to develop services for the prevention of child and adult obesity as well as the treatment of child and adult obesity including bariatric surgery.

Five informants out of the total sample of 23 in the first case were actively involved in the implementation of the Obesity guideline, including the Director of Public Health (PCT), the Assistant Director of Public Health (PCT), the Director of Commissioning (PCT), a Chief Dietician (PCT), and one hospital consultant from the local hospital. Similarly five informants out of the sample of 25 in the second case-study were also actively involved in the implementation of the Obesity guideline including a public health manager, a project manager, a GP and two nurses. The remaining informants in both case studies, as with the CHF guideline, consisted of managers with strategic rather than operational responsibility for the implementation of all NICE guidelines and clinicians, who may have put them in to practice.

Following publication of the Obesity guideline, a number of changes were introduced in primary care for the *prevention* of obesity in adults and children across both case studies. Forward planning meant proactive, rational and strategic arrangements that were crucial for the implementation of the guideline, anticipating the future implementation costs of training and of the upgrading of the skills of potential adopters, such as practice nurses.

> We forward plan our implementation approach including strategic plan assessing costs of actually doing training with individual practices. Our next step is to develop a workplace programme involving the local authority and look at interventions with community centres promoting and supporting healthy lifestyles. (Assistant director of Public Health, case-study/1)

> Our obesity strategy was written in 2005, and one of the recommendations was to revise it according to the NICE guideline and establish the obesity steering group. (Public health manager, case-study/2)

In both case studies it was emphasised that the implementation of the NICE guideline's recommendation for the treatment of obesity via bariatric surgery, an expensive procedure, was somehow neglected. It was emphasised that adherence to the recommendations for bariatric surgery was not feasible because the cost of its implementation was perceived by senior managers as prohibitive, threatening their organisation's financial solvency. One bariatric surgeon explained that the surgery was not commissioned from the local hospital by the PCT due to the heavy investment that was required to comply with the Obesity guidelines. The argument put forward was that the local PCT managers had kept the issue off the decision-agenda:

> The difficulty that we experience is that the provision of the service that would be regarded as complying with NICE guidelines is partly down to money. The money was not there to spend. So if you do not address the problem you do not have to spend the money. (Bariatric surgeon, case-study/1)

Given that the treatment of obese people according to NICE guideline required major financial investment, it might be suggested that senior commissioners decided to keep the issue off the agenda for a time, feeling that 'open' admission access of obese patients to the local hospitals might be prejudicial to their fiscal position and ability to meet fiscal targets. 'Open' admission might also require rationing in terms of how to select or prioritise patients, and this might have attracted negative local and/or national media attention. It was also suggested that bariatric surgery should not be seen as a legitimate option for treating obesity, and thus it was neglected:

> Obesity is a lifestyle disease: you cannot address the issue with medical treatment. In order to help these people you need to change their lifestyle. So we are focussed on prevention of obesity, education of patients and change of their lifestyle, and not bariatric surgery. (Director of Public Health, case-study/1)

Similarly, in the second case-study, the PCT's pathways for obese patients in need of bariatric services were vague and ambiguous, and possibly reflected the influence of higher priorities and thus potential conflicts. The impression given was that local policies for the implementation of NICE guideline were not intended to be fully operational:

> One of the barriers that we have in referring patients that we think are in need of bariatric surgery is that we don't have detailed knowledge of the pathway of referral. You could argue that it was done on purpose: they don't want the channels of communication to be clear, because bariatric surgery is a fairly expensive one. So they may want to keep the numbers low. It certainly happened with a colleague of mine from a different hospital. They agreed with a PCT to follow the NICE guidelines and the aim was to do 10 producers per year, but within a very short space of time they were doing 250 a year and the numbers went up and up and the PCT then altered the contract, changing the BMI levels from 35 to 40 – ignoring NICE guidelines, rationing the service, but not based on what the patients needed. (Senior endocrinologist, case-study/2)

During the second phase of the first case-study it was emphasised that the process was less controlled. Forward planning of the implementation of the Obesity guideline was not sufficient to increase its uptake, emphasising that the uncontrolled aspect of the process arose from the negotiations between the doctors and managers who were

affected by decisions. For example, it was important to negotiate contracts with GPs to provide a more structured approach to measuring patients' body mass index (BMI) according to the NICE guideline:

> We negotiated with the PCT about introducing a target around that indicator, wanted 70% of GPs' patients with the BMI recorded but for some reason it was all dropped. (Assistant director of Public Health, case-study/1)

In contrast, informants from the second case-study emphasised that the absence of strong clinical leadership for this team meant that it was a slow and difficult process to command adequate fiscal resources and scarce time. It emerged that adherence to earlier plans had not been feasible. The informants' time was taken up by priorities imposed by the PCT Board, progress in the implementation of NICE guidelines came to a standstill when attention shifted away, implementations plans had to be abandoned and it became redundant:

> We did not have a director of public health with us for a long time. For me, I very much know what I want to do, but I am not able to influence high-level senior managers. We have not reviewed the obesity strategy. Likewise the obesity steering group never got off the ground. We have to do other evaluations that have been requested by the PCT Board linked with obesity but not necessary with the NICE guidelines. Its implementation is not a priority any more. (Public health manager, case-study/2)

4. Discussion

The aim of the study was to explore how local healthcare providers and organisations respond to NICE clinical guidelines; the nature of the process by which clinical guidelines are implemented, examining how they are introduced, received and used by front-line providers.

This study has shown that the NICE guidelines implementation process has both planned and emergent components. The introduction of NICE guidelines into the NHS Trusts seemed to be at least in part a linear process. The early stages did indeed resemble what theory calls the 'planning phase' of the implementation process [44], and were found to be controlled, staged and in accordance with rational models of implementation, where responsibility for the overall implementation of a programme, policy or project rests with the organisation's management. Strategic planning was seen as essential to assure adherence to NICE guidelines, and included activities such as development of local guidelines, dissemination activities to raise potential adopters' awareness, updating and monitoring local guidelines' use in everyday practice. To undertake all this required considerable time, authority and financial resources. By contrast, the latter stages of the process became uncontrolled, were subject to unpredictability of outcomes, and generally proceeded in a non-linear [45,46] way from the planning phase to adoption in everyday practice, especially in entailing a bidirectional relationship between planning and evaluation as well as multiple interactions between managers and doctors. 'Movement' went back and forth between planning the implementation and evaluation of the strategies used by those responsible for implementation. The outcomes of these strategies were not predictable and were distinctly different across the cases studied. This lends support, at least in this context, to those who have suggested that implementation, rather than being staged, smooth, straightforward and linear, is actually more interactive and disorderly [47,48] which reflected the influence of powerful interest groups and resulted in the decision-making processes being characterised by bounded rationality and political influences [49].

In addition, the findings suggest that sustaining implementation of the NICE guidelines was difficult, owing to divergent perceptions of successful implementation outcomes. These perceptions were shown to have influenced doctors' and managers' receptivity to engage (or disengage) with organisational initiatives for the implementation of NICE guidelines, and, consequently, influenced the shape of the implementation process. This finding points to abstract and ambiguous measures of adherence of NICE guidelines at the national and the local level. This ambiguity seems to create uncertainty in guidelines implementation.

One of the key findings of this research is that while the national policy context was the same across the both case studies, the variations in the implementation could be best accounted for in terms of differences in the structure and nature of the local organisation context, particularly in the local implementation teams responsible for putting the NICE guidelines in practice. The latter includes the distinctly different characteristics and status of the key actors involved in implementing both NICE guidelines and use of incentives to adhere to the guidelines. For instance, the informants' accounts of implementing the CHF NICE guideline in the first case study and the obesity NICE guideline in the second suggest that changes to the implementation team's management structure, in combination with changes in the organisations' priorities, were of importance for understanding why the implementation process was characterised as planned in its earlier phase becoming unpredictable in its later phase. In contrast, the informants' accounts of implementing the CHF NICE guideline in the second case study and the obesity NICE guideline in the first show that their implementation were sustained over the longer term. This was due both implementation teams being better positioned to manage the uncertainty in the direction and outcome of the implementation by mutual adaptation of planning, evaluation and the adoption new work routines. Hence, future studies of implementation should focus on a more detailed exploration of the local implementation group and how they are constituted and structured.

The value of financial incentives for increasing adherence to NICE guidelines lends support to current government policy, which aims to incorporate NICE guidelines into quality standards using financial incentives and sanctions [50] and to devolve commissioning to GP consortia [51]. These contextual 'factors' determined the implementation groups' capacity of to effect the desired changes over time. Implementation was not a single event, nor one single decision; rather there were numerous decision events

performed by many people across different organisational levels and time. However, the key influence on the shape of the implementation process and the extent to which the guidelines were taken up hinged on the decision by key informants to continue to make its implementation a priority. This was best illustrated by the CHF guideline in the second case study, where the local implementation group, because of its structure and composition, managed to sustain its implementation as a high priority for both health organisations.

5. Limitations and strengths

The prospective and longitudinal design adopted in this study enabled the shape and nature of the implementation process and the influence of the local organisational context to be identified more systematically. However this study also had its limitations.

First, the data presented here derived only from the analysis of the interviews with key stakeholders. Ideally these data could have been triangulated against observation of strategic meetings and analysis of documents about local implementation policies and practices [52]. Secondly, the fall-out between the two rounds of interviews, mostly due to time limitations, raise doubts about the representativeness of the findings, since it is difficult to know whether those who were not re-interviewed may have responded in a different way. It was recognised beforehand that with such a design it would be not feasible to retain the sample of informants in both case studies, given that it was not an experiment but a 'real life' study in an uncontrolled environment. (Nevertheless, most informants directly involved in the implementation of both NICE guidelines were interviewed twice.) Thirdly, the sample of doctors who were interviewed may not have presented views representative of all, since most were senior hospital doctors or senior GPs with greater discretion and influence. If younger less experienced doctors had been involved in the studies, the findings may have been different, in that acceptance of NICE guidelines would probably have been greater, as they had an incentive to adopt NICE guidelines as a defence against complaints and malpractice lawsuits. Finally, this research was also limited due to the type and location of the NHS Trusts. For example, NHS Trusts involved in research, teaching and training might have mechanisms in place to assure 'faster' knowledge mobilisation, and thus, expedite the pace of implementation than in non-teaching NHS Trusts.

6. Conclusion

Given the coalition government's proposed reforms for health service [51] and the current financial climate, the significance and utility of NICE in regulating cost-effectiveness is greater than ever [53]. However NICE and other national health policy-makers need to recognise that the introduction of planned change 'initiatives' in clinical practice is subject to social and political influences at the micro level as well as the macro level.

The importance of the organisational context also points to the significant influence of managers in the implementation process which has seen to be neglected in previous research, as the focus has been on changing professional practices [54]. The implications of the implementation process being shaped by negotiations between managers and clinical professionals are important because it suggests that the authority, resources, and ability to influence the implementation of 'new evidence' are dispersed across multiple actors, levels of hierarchy and decision-making *loci*.

Conflicts of interest

None.

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