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"Local decision-makers views' of national guidance on interventional

procedures in the UK"

Authors: Tania Lourenco, Adrian Grant, Jennifer Burr, Luke Vale

ABSTRACT

Objectives: To identify how NHS decision-makers manage and perceive NICE

interventional procedures guidance (IPG) and to determine whether there would be

additional information that would be useful to present to decision-makers.

Methods: Qualitative study using one-to-one semi-structured interviews. The

framework approach was used to analyse the data generated from 14 participants,

and emergent themes coded. Data were analysed separately for providers and

commissioner organisations.

Results: Perceptions about how IPGs are managed in provider organisations varied.

Some decision-makers considered that guidance is handled very well. Others think

that management is suboptimal and haphazard, and it is unclear about whether

clinicians follow procedure for cautionary guidance. In commissioner organisations,

IPGs are not seen as a priority by most and are not considered an area that will soon

enter routine clinical practice. Moreover, commissioners felt that IPGs lacked

relevance as there is no consideration of whether procedures are cost-effective or

affordable. In general, respondents perceive that the content and quality of guidance

is satisfactory. To different extents, useful additional types of information for inclusion

in guidance would be: prevalence, incidence, cost, patient views, consequences of

using the new treatment, comparative information, effectiveness and cost-

effectiveness.

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Implications: Results indicate that management of IPGs in the NHS can be improved. These results are important to understand the usefulness of IPGs and how they meet decision-makers' needs in the NHS.

INTRODUCTION

New interventional procedures are often introduced in a variable and somewhat uncontrolled manner. Following concerns described in the Bristol Inquiry (Kennedy report),¹ a programme of work within the National Institute for Health and Clinical Excellence (NICE) was established to improve and regulate how these procedures enter routine clinical practice. Since 2003, the Interventional Procedures Programme has provided guidance on the safety and efficacy of new interventional procedures to decision-makers in the National Health Services (NHS) in the United Kingdom (UK)² The guidance includes a description of the technology, a summary of results and the type of recommendation made by the committee (normal, cautionary, research only, should not be used).³

Interventional procedures guidance (IPG) is not mandatory and therefore it is the responsibility of each organisation to implement them. As the success of this Programme is dependent on appropriate engagement from the NHS,⁴ this study was designed to explore how NHS decision-makers respond to IPGs. We also aimed to: (1) identify how decision-makers perceive IPGs; (2) identify key problems related to IPGs, as perceived by NHS decision-makers; (3) determine whether there would be additional information that would be useful to them; and (4) offer insights in how IPGs can be improved.

METHODS

Participants and setting

As healthcare delivery is organised differently across the UK, a purposive sampling strategy was adopted to select NHS employees in England, Wales and Scotland representing different roles, types and sizes of practices (Table 1). This sample was chosen to describe a range of knowledge interpretation and general awareness. The sampling frame consisted of 18 decision-makers selected using three strategies: a list of known committee members of the Interventional Procedures Programme hosted at NICE; an NHS network group with an interest in public health; and snowball sampling of key participants involved in decision-making on prioritisation of treatments in the NHS. A recruitment letter with details about the study was e-mailed to every person contacted.

Data collection

Data was generated from NHS decision-makers using one to one, face to face semistructured interviews, at a time and venue convenient for the participant. Prior to the interview, participants received a 'participant information leaflet' explaining study's objectives and purpose of the interview. All participants signed a consent form at the beginning of the interview. Using an interview topic guide, participants were asked open-ended questions exploring (1) how IPGs are handled in their place of work in terms of process, dissemination and monitoring; (2) their perceptions about IPGs; and (3) problems and improvements related to the guidance, including additional types of information that could be added to guidance. Following the interview, participants were also asked to rate on a visual analogue scale (VAS) ranging from zero to ten, how much they would value different types of information if it were added to the IPG. They were also asked to rank which types of information would be most useful at the time guidance is issued. The different types of information can be seen in Figure 3. The ranking exercise was designed to identify not only what would be useful to have, but also, what is it that decision-makers really want. Data were digitally recorded and transcribed verbatim.

Data analysis

Data was entered into NVivo (v.7 computer software, QSR International, Melbourne, Australia) for coding and analysis using techniques drawn from the framework approach.^{5, 6} A coding frame was developed based on our initial research questions and emerging themes from the transcripts. Two researchers systematically coded the transcripts. Thematic categories were developed by further refining the initial coding frame and thematic charts were checked by at least one other researcher within the team. Disagreements were resolved by consensus or arbitration. Data obtained from the VAS and ranking exercise were subjected to descriptive analyses. Medians were calculated and radar diagrams were plotted.

Different organisational arrangements of the NHS are in place in England, Scotland and Wales, however, regardless of country, NHS organisations can be broadly divided into commissioner and provider of services. Decision-makers' views for both types of organisational arrangements were explored, and a stratified data-analysis was conducted in order to identify potential subgroup differences in how IPGs are handled and perceived by commissioners and providers.

RESULTS

Out of the 18 decision-makers contacted, 15 replied and agreed to be interviewed, although an interview time could not be set for one. Fourteen interviews were conducted by one researcher (TL) over a period of four months in 2008. The sample varied in relation to setting, type of organisational structure (commissioner or provider) and role in the decision-making process (Table 1). Respondents were widely dispersed: nine from England (six of ten Strategic Health Authorities), four from Scotland and one from Wales.

Dissemination and management strategies of interventional procedures

guidance

Provider organisations

Figure 1 describes the different patterns in which provider organisations manage IPGs. Three main pathways of guidance dissemination were identified. In four centres, all guidance is disseminated to relevant clinicians by a designated individual or a committee/group within the organisation. In one centre, a designated individual within a committee/group circulates only cautionary guidance. In two centres, an internal system for dissemination of guidance did not appear to exist and clinicians in these centres received guidance directly from NICE.

In general, following circulation of guidance, the committee/group or designated individual expects feedback from clinicians on the status of the procedures in their organisation, or whether they would like to provide the procedures. For example, one respondent explained that:

D114: "All the guidance that is produced by IPAC, which is relevant to the trust... gets forwarded to the lead clinician... and it is expected that they actually feedback what they find..."

In five centres, for procedures with 'cautionary' guidance (see Figure 1), a group/committee is expected to agree and decide on the implementation criteria. If the procedure has cost-consequences while appearing to provide additional benefits to patients, or had the potential to improve survival, then a business case would be prepared by the clinician making the request.

Monitoring to ascertain whether new procedures are introduced appropriately and clinicians are compliant to the implementation criteria differed between respondents. Some audit all procedures; others audit only procedures where NICE interventional

procedures programme has issued 'cautionary' guidance. In one centre the first 20 cases are audited before a final decision is made. Another centre has a database that lists the names of the clinicians credentialed to do NICE interventional procedures. If a name is not in the database, then that person should not be allowed to perform the procedure.

One centre however seemed to lack a structured process in the method in which IPGs were managed:

K120: "(...) I'm not sure it has a formal mechanism to react to it...I'm aware they receive them, but I'm not sure that anything then happens... I think that the expectation is that within each specialty people will pay attention to them."

Commissioner organisations

Figure 2 describes the different patterns in which commissioner organisations manage IPGs. In terms of dissemination, commissioners receive guidance directly from NICE. In three centres, this is then circulated across the organisation. In four centres, guidance is also circulated to relevant clinicians and it is expected that they will provide feedback on the status of the procedures in their organisation or whether they would like to provide the procedures is expected:

H118: "(...) the interventional procedure guidance comes into the commissioning part of the organization and we have a group that is set up that... decides which provider it is relevant for and sends it to the provider for them to feedback to the commissioner."

In four centres, after guidance is disseminated, a business case would usually be prepared and presented to the commissioner organisation if the clinician wants to provide the procedure.

In terms of monitoring, three centres actually monitor the uptake of procedures with IPGs. One centre expects that in the future, information about the number of procedures with guidance, and how they are performed, will be collected. A lack of a structured process in the method in which an IPG is managed was identified in one centre.

Although the majority of centres seem to have a process to handle IPGs, the general impression was that the commissioner organisation works in a reactive manner, as one participant said:

Q125: "So we wait for NICE... to issue guidance and we wait for people to put in requests then we begin to respond, as opposed to doing things more proactively..."

Perceptions about management and importance of guidance

Provider organisations

Some decision-makers considered that guidance is handled very well and an active system within the centres exists to respond to guidance. However, one participant felt that guidance could be better managed (especially for monitoring) if there were more resources available. Others thought that management was suboptimal and haphazard and it was unclear about whether clinicians follow the procedure for cautionary guidance:

B112: "I think is rather haphazard. I don't think we really have a good method...I'm not sure that the trust is really taking it on board."

One participant noted that guidance is increasingly seen by consultants as a support material to get procedures approved:

B112: "...I've noticed more recently when consultants are submitting their evidence, will quote the NICE guidance if it supports what they want to do. So, I

think they're learning that it's [NICE guidance] actually there to support them more often than not."

Furthermore, IPGs were described as a method of confirmation to clinicians who already perform the procedure, and to inform patients and those clinicians who have never performed it:

N123: "...it's confirming to people that are... using that procedure already that you are absolutely fine by doing that. It's a kind of a confirmation as opposed to an introduction... what it is trying to do is to tell the wider institution about these procedures, and maybe patients who might be thinking about them or indeed maybe general practitioners that might need to know a bit, or maybe, say generalists, who might not have started doing those procedures."

Commissioner organisations

IPGs are not seen as a priority by most. Respondents expressed that this is because this guidance does not have the same mandatory nature as NICE technology appraisals have in the NHS within England:

C113: "...we're more interested in technology assessment [appraisals] more than IPGs, because IPGs are not compulsory for the NHS."

However, one participant highlighted IPGs as a way of identifying areas for future research rather than technologies that will soon enter routine clinical practice in the NHS.

Q125: "My perception is that we look at an area that NICE has issued good practice guidelines for further applied research; that this is not an area of work that will be routinely brought into practice in the NHS at the present time."

Many respondents were concerned about the lack of relevance of IPGs to the commissioners as they do not inform commissioners whether the procedure is cost-effective or affordable:

C113: "But for IPGs, it's 'safe' and 'efficacious', OK, that's nice to know, but I need to know if it is cost-effective, if it is affordable, who to give it to, and so on."

Perceptions about content and quality

Provider organisations

Respondents perceived the content and quality of IPGs as satisfactory, adding that the quality of guidance is often dependant on the quality of the evidence available:

B112: "I think they're fantastic! ...I think that the advice is practical without being too restrictive... The quality of the recommendations depends very much on the quality of the evidence..."

Commissioner organisations

In general, respondents at commissioner organisations perceived that the content and quality of guidance is also satisfactory. One added that guidance is 'useful' and 'educative':

G117: "They can be quite useful; ...it has been quite an educative experience. In terms of what they do... they're fine."

However, there were arguments that the content of guidance is not applicable to commissioner organisations. This was also supported by two additional respondents adding that important information about costs and cost-effectiveness is absent:

C113: "...the most important thing is the cost-effectiveness... that's why they're [IPGs] not very useful in everyday life..."

Although they broadly thought guidance was adequate, commissioners felt that it was unclear whether the procedure is applied research, or is already in practice, and whether the procedure is being recommended by NICE or recommended on the possible introduction on safety and governance issues:

Q125: "I think they're fine as far as they go, but they don't spell out the fact that this is about the introduction of a new technology... the impression I feel... is that this is

being recommended by NICE as opposed to this is guidance on the possible introduction on safety and governance issues around introducing this. I think that the balance between whether this is research or applied research and whether this is under practice isn't spelt out and I think that NICE guidance gives a false impression."

Perceived potential barriers to effective response to guidance

Provider organisations

It was highlighted that it is difficult to monitor procedures with IPGs within provider organisations, as these are not coded.

A111: "For example code for coblation tonsillectomy. That is something that there were great concerns over. It's only one way of doing tonsillectomy and it doesn't show through in the coding and there's no way of telling from the data the hospital collects how many coblation tonsillectomies are occurring..."

It was also noted that some clinicians felt that guidance affects their clinical freedom, potentially creating some resistance in taking on board trust procedure. Moreover, there have been concerns about how IPGs are interpreted, suggesting a degree of ambiguity in the guidance:

B112: "The problem is sometimes people don't read the guidance properly and they put their own interpretation on the wordings... people tend to read what they want to read, they will interpret it as NICE has damned this when actually hasn't."

Other problems were related to how NICE interventional procedures advisory committee (IPAC) is regulated and set up, and concerns about its representative nature were expressed:

F116: "Another thing about the IPAC is probably the representative nature of the committee... there's an awful lot of white middle aged men on the committee! It's not perhaps as diverse as it should be!"

Commissioner organisations

The main problem perceived by commissioners was that IPGs seem to lack context, consider procedures in isolation, and lack prioritisation:

G117: "...it looks at something small very much in isolation, and the overall kind of place in the overall treatment is often quite important, so you need to know whether this is something that would be absolutely first line, and would be the treatment for everybody... That's not always clear, especially when you start getting into some tertiary level stuff where you're really not sure how exactly a patient has been treated."

Q125: "...there is lack of prioritisation within the NICE process... they've just issued a guidance on all these new technologies over the year as if they were all likely to be of equal benefit."

There were also concerns about the ambiguity of guidance. A couple of respondents noted that there is confusion regarding the status of IPGs, giving rise to external pressures:

Q125: "...we had a request from the patient and his GP... They quoted the fact that NICE had issued interventional procedures guidance about this [a procedure] and they took that as a sign of approval the fact that NICE had made some recommendations about audit, about governance, about the introduction of an interventional procedure. They took that as overall approval of the procedure and... think PCTs should commission it. "

Suggestions for improving response to guidance and its content

Provider organisations

Some respondents felt that better management plans within provider organisations are required to deal with procedures with an IPG:

B112: "...we should have somebody sifting through it all, making sure that procedures that have cautionary guidance are being used or not and then having fairly robust methods of checking that... people are following the guidelines..."

More robust mechanisms of monitoring were felt to be imperative. The need for efforts from NICE and the OPCS (Office of Population Censuses and Surveys) to identify codes for NICE interventional procedures was highlighted by one respondent. This was considered necessary for an improved monitoring of such procedures. Moreover, one respondent suggested that decision-making about the introduction of a NICE interventional procedure should become more centralised since the decision-maker who holds the budget, does not often realise the impact of such procedure at the individual clinical units. Guidance should be circulated not only to relevant clinicians, but also to those who are responsible for budget allocation.

N123: "I think that the dissemination to certain managers that hold the purse strings might be useful so that they know that this might be needed."

Moreover, one respondent stressed that there should be better support mechanisms from NICE or the government regarding the implementation of guidance at provider organisations:

A111:"I think the big fault of all... government initiatives is that it stops at the guidance, and very often there isn't any real help to implement things. There isn't any real look to see how well they've been implemented... NICE puts out this information, but it puts out into a vacuum and how individual trusts deal with it is up to them."

Although quality and content of guidance was described as being satisfactory, respondents felt that additional information on top of what is currently provided in the guidance would be useful. It was noted that there are issues surrounding the production of business cases. One respondent would like to see more readily

available information to help inform business cases, and suggested that NICE could produce some relevant information to help procedures being introduced.

N123: "it would be extremely helpful from a clinician point of view, when we're trying to improve patient care and also introduce interventional procedures, if they [NICE] could even produce the business case in a way, and help us that way. Because they obviously looked at that information... they may not need to put it in a summary or whatever, but they could say, if require information with regard to costing things, you know, somewhere where you can get it."

Another cited that it would be useful to include in the guidance information about whether the speciality associations agree with NICE's decision, and details about what other centres are doing:

K120: "...it would be useful to know whether the specialty association... agrees as well that this is a reasonable thing to be doing... It would be nice to get some input from a number of centres around the country as to how many they're doing, what the outcomes are, and to be able to talk to other units that are doing it."

In general, respondents felt that in terms of additional types of information, they would like to see information on costs of the procedure as well as the number of patients affected:

E115: "the areas where we need to go looking for more information surround all the business case arguments, so the cost, the number of patients, etc, but on the other hand it is not within IPAC's remit."

Also, one respondent mentioned that it would be useful to have more comparative information between treatments:

D114: "I think the area of weakness is that there isn't a comparison data between the two different procedures... it would be more useful to have more comparative data."

These findings are consistent with those from the VAS and ranking exercises. In general, respondents rated that all types of information that were proposed would be highly useful if included in the guidance. However, following the ranking exercise, the three most valuable types of information that could be added to the guidance are: 'number of patients affected', 'consequences of using the new treatment', and 'effectiveness' i.e. how it works in standard practice compared with standard management (Figure 3).

Commissioner organisations

One respondent would like to see better monitoring of NICE interventional procedures, but the majority were unclear about what can be improved in the current management of IPGs. However, they expressed improvements related to the content of guidance. Like providers, one respondent cited that it would be useful to know what other centres are doing and wondered whether NICE would be prepared to include that sort of information in the guidance.

C113: "Something that is useful would be what happens around the country. What other PCTs do... When we get the requests from the clinician, they tell us 'oh, everybody else is doing it, apart from you!'."

In order to help decision-makers make judgements about likely benefits and give an indication of hierarchy between treatments, one respondent would like to see a linkage and a comparison between guidance that was issued for the same clinical problem:

Q125: "NICE have issued guidance in the last two or three years on foam sclerotherapy for varicose veins, radiofrequency ablation for varicose veins and laser treatment for varicose veins... they've issued them all independently even though they're all for treatment of varicose veins... if they're going to issue guidance in a number of new technologies in one clinical area, I can't see why they couldn't reference the other guidance... Even if it wasn't an absolute judgement,

they could give some indication of the hierarchy, what's likely to be superseded? Is there poor benefits?"

Also, it was noted that it would be useful if NICE could give an indication of what treatments are not worth doing:

C113: "it might be more useful if they had at least what definitely is not worth doing."

Another respondent felt that IPGs should provide more detail about the likely status of the procedure in the NHS and that NICE provides advice to the NHS as a whole not just to individual clinicians:

G117: "...Given that NICE is for advice to the NHS... they should be looking at the importance to the commissioning body as opposed to advice to the individual clinician because they're giving advice to the NHS and sometimes that gets forgotten and the commissioning body is not an expert in every minor detail in what goes on in a clinical treatment."

In general, decision-makers suggested that NICE IPGs would be more useful if they gave and indication of the cost and if they went beyond efficacy to effectiveness and cost-effectiveness if the evidence exists:

C113: "The most important thing is the cost-effectiveness. They don't look at that. That's why they're not very useful..."

G117: "...last week we had two that we were looking at the IPGs partly because is just to say 'is there any objective evidence on the safety and efficacy, particularly efficacy for individual patients?' But it still doesn't help us because of cost-effectiveness.

Also, some respondents would like to see details about the prevalence and incidence of the condition because such information is not readily available and without this, it is difficult to make a decision as to whether a procedure should be implemented or not.

Moreover, two respondents cited that guidance should incorporate patient and carer views.

P123: "[it would be useful to provide] a more detailed evaluation of an assessment of what the views are of patients and their carers who may be involved."

Based on VAS responses, all types of information were thought to be highly useful, but the ones that they would value the most were: 'number of patients affected', 'cost of treatment', 'effectiveness' and 'cost-effectiveness' (Figure 3).

DISCUSSION

This study is the first to explore how decision-makers in the NHS manage and perceive IPGs. It identifies some potential barriers to the successful implementation of IPGs and identifies areas of improvement.

The findings of this exploratory study suggest that the process in which IPGs are managed varies between countries, centres and type of institution. It was found that guidance appears to reach commissioners and providers and in most institutions there are efforts to have a structured process of response for IPGs. However, having a process in place does not necessarily mean that the procedure is followed as this depends on the value that decision-makers place on this type of guidance. Promulgation of guidance has been shown to have little effect on practice. The patterns of management identified in our research describe organisational responses to manage the implementation of new interventional procedures. In terms of perceptions, the management of guidance is suboptimal; there is a lack of a structured process in some centres; and there is resistance to conform to guidance. This indicates that improvements are required in how IPGs are handled and perceived in the NHS. Another point for analysis is whether commissioner

organisations should have a role in the management of IPGs as these are generally perceived as low priority and lacking relevance.

There seems to be confusion about the status of IPGs, which provide guidance about the safety and efficacy as opposed to NICE Technology Appraisals Guidance, which provides assessments about the effectiveness and cost-effectiveness of procedures. Compliance with the latter type of guidance is mandatory in England and Wales. Our study suggests that there needs to be an improvement in how the different types of recommendations in an IPG are perceived and the role of the Programme requires better understanding.

An interesting finding arising from this study was that the purpose of an IPG can be perceived as nothing more than a method of confirmation to those already performing the procedure, or as information to generalists and patients about the existence of such procedures. It was also noted that guidance can be perceived as a 'good practice guideline' rather than something that would soon enter routine clinical practice. These perceptions go against the purpose of this type of guidance as delineated in the 2003 health services directive.⁴

It was perceived that monitoring is an area that needs to be improved for effective management of procedures in the NHS. The main factors that seemed to contribute to ineffective monitoring were: lack of coding, registries and resources.

In general, the content and quality of IPGs was perceived by providers and commissioners as being satisfactory and that they addressed their remit. The respondents from commissioner organisations expressed concerns that question the suitability of such guidance to this type of organisation. One concern was the ambiguity of guidance. It was also unclear whether the procedure is in practice or is

research. Another concern was the lack of context and prioritisation in guidance. Commissioners expressed that IPGs look at procedures as if they are likely to have equal benefit. It is unclear if these findings will be generalisable to all commissioner organisations, but are perhaps to be expected in an NHS environment, where there are multiple competing objectives which make decision-making complex. Interestingly, although commissioners felt that knowledge about cost-effectiveness would be a good thing to add to guidance, they seemed more concerned about the lack of information on prevalence, costs and comparative information between treatments. Despite the perceived value of cost-effectiveness data, decision-makers at provider organisations would also like to have more readily available information to help inform business cases. This includes information about prevalence, the consequences of using the new treatment, and effectiveness. Adding such information to guidance would improve how decision-makers value and perceive this type of guidance.

It was highlighted that NICE should be reminded that it provides advice to the NHS as a whole and not just for individual clinicians, and therefore, more information around the procedures is required as guidance will also be considered by decision-makers who dot have a clinical background.

This study illustrates how decision-makers in the NHS value the concept of transparency. There were remarks about the representative nature of people sitting in the advisory committee, and how they are selected, as well as whether individual medical speciality associations endorse the recommendations issued by NICE. Also decision-makers highlighted that they would like to know which treatments are offered in other centres. If there were national registers and appropriate coding available for all NICE procedures, then this type of information could be more easily retrieved.

Strengths and limitations

The use of a qualitative approach was an appropriate method to explore how IPGs are managed in the NHS. In comparison to a quantitative survey, it allowed a detailed exploration of a complex area making feasible the identification of decision-makers' perceptions about guidance and the identification of problems and likely improvements related to guidance.

The study allowed us to evaluate the needs of NHS decision-makers in terms of what would be useful to be added to the guidance to improve decision-making about the introduction of new interventional procedures. By using a ranking approach with incorporated monetary cost for obtaining each type of information, it allowed the identification of information that is genuinely useful given the constrained resources available to the NHS. Moreover, participants came from a diverse background reflecting different cultures and organisational structures within the NHS, making findings relevant to the wider UK context.

The study relied on perceptions and experiences of decision-makers, therefore actual practice may differ. Also, five out of the seven participants interviewed in the provider organisations are members of the NICE Interventional Procedures Advisory Committee. It is possible that participant's exposure to decision-making in relation to interventional procedures may have been atypical and therefore their views might not be representative of the NHS as a whole. Although the sample size was purposively identified, it is possible that radically different approaches might have been identified, had more people been interviewed. There was, as described in the results, a degree of consistency between interviewees. Overall, our interviews enabled the identification of a range of knowledge interpretation and general awareness towards NICE Interventional Procedures Guidance, which was our purpose.

Conclusion

It is important to note that decision-makers did not express widespread dissatisfaction with IPGs and some very positive perceptions were reported. However, this study suggests that there is a disparity between what is happening and what should be happening and that guidance from the Interventional Procedures Programme may not be having the desired impact. This study therefore suggests that the management and perceptions of IPGs could be improved.

Competing interests

None.

Ethical approval

Not required.

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