Title: A qualitative study of the relationship between the Scottish Medicines Consortium and their clinical experts.

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Structured Summary (248 words)

Aim: Internationally, health technology assessments (HTAs) are ubiquitous drivers to health policy. Within Scotland, the Scottish Medicines Consortium undertakes the medicine review process. Input from clinical experts, involved in frontline care, is an integral component of the assessment process. This paper explores the relationship between the clinical experts and the HTA agency within Scotland to better understand what motivates expert clinicians to devote their time to the medicine review process with no remuneration.

Methods: 27 clinical experts from 16 different clinical specialties took part in one-to-one interviews at their place of work between October 2011 and March 2012. Data analysis was inductive and comprised the organisation of data into a framework and a subsequent thematic analysis.

Results: Three distinct themes were identified: (1) recruitment which identified two types of explanations for the experts' appointment: external justification (nominated by another) and internal justification (being recognised as an expert); (2) flexibility of the procedures, with experts able to determine their own response style and negotiate timelines; (3) healthcare systems, demonstrating that their affiliation to the health system underpinned the relationship and their motivation to be clinical experts.

Conclusions: The findings of this study provide insight into the elements important to clinicians who voluntarily contribute to HTA processes. Examination of these elements in the context of the organisational citizenship behaviours (OCB) literature provides a foundation on which to improve understanding of this relationship and sustain and improve clinical expert participation in an increasingly intensified clinical environment and within cash-limited HTA systems.

Introduction

Health technology assessment (HTA) is a multidisciplinary activity that scrutinises the safety, clinical and cost-effectiveness of health technologies including medicines [1, 2]. The aim of HTA is to provide evidence-based information to inform the use of health technology and allocation of resources. The 1980s and 1990s saw a proliferation in the number of European HTA organisations, with the first HTA agencies appearing in France, Spain and Sweden. This was followed by the Netherlands, Austria, Finland, Latvia, Denmark, Norway, Germany and the United Kingdom[3]. By 2008, 16 European countries had formal HTA organisations[4, 5] and today the number of HTA agencies continues to grow across Europe [6].

The structure, role and processes of HTA agencies vary between countries but can broadly be divided into 2 groups: (1) agencies providing an advisory or regulatory function, often aligned to re-imbursement; and (2) independent review agencies generating HTAs to support clinical practice decisions [1]. For example, in France and Sweden, HTA is used to support reimbursement decisions while, in Scotland, the Scottish Medicines Consortium (SMC) provides advice to the National Health Service (NHS) about the comparative clinical and cost-effectiveness of medicines. Similar to SMC, the National Institute for Health and Care Excellence (NICE) provides advice on new medicines to the NHS in England in addition to clinical guidelines, social care guidance, and interventional procedures guidance.

Good practice for HTA dictates that key stakeholders who may be impacted by the HTA decision must be engaged with in order to improve the quality, relevance and acceptability of HTA [7, 8]. Failure to do so may delay implementation of HTAs due to appeals and disagreement amongst stakeholders [1]. Stakeholders vary according to the role of the HTA agency but often include policy makers, health professionals, patients, and industry [9]. Of these stakeholders, health professionals are of particular importance as they may be involved at a number of stages in the HTA process: topic nomination, review of the evidence, development of the HTA report or appeal of the HTA decision [10].

In Scotland, the SMC recruits healthcare professionals as clinical experts. These are consultant physicians, surgeons, specialist pharmacists and general practitioners who are contacted at the beginning of the medicine assessment process. The clinical experts provide contextual information on current prescribing practice, disease prevalence, unmet clinical need and product fit within clinical practice[11] and gives a vital opinion about a proposed new medicine's use "at the coal-face". However, this is not an explicit part of the clinician's professional role, offers no remuneration or direct reward, and is voluntary with limited external pressure as the recruitment process is anonymous. The need to understand the mechanisms behind this behaviour is two-fold. Firstly, by developing an understanding of the relationship, clinical expert input to the medicine review process may be sustained and even increased within HTA generally. Secondly, due to the financial limitations within which all health care providers operate, through understanding the dynamics within the SMC it may be possible to export the model of voluntary clinician engagement into other healthcare activities.

No research within health care has examined this relationship in HTAs but the field of psychology could provide a framework from which to consider clinicians' engagement. Organisational citizenship behaviour (OCB) is defined as "*individual behavior that is discretionary, not directly or explicitly recognized by the formal reward system, and in the aggregate promotes the efficient and effective functioning of the organization*"[12]. Organ and colleagues propose five dimensions within OCB: altruism, courtesy, conscientiousness, civic virtue, and sportsmanship [12]. These dimensions are widely used within the literature, although not universally accepted [for example 13], and offer a basis from which to explore clinician engagement within HTAs. For our purposes "civic virtue" is most relevant as it includes organisationally focused behaviours such as the attendance of non-mandatory meetings, an interest in the organisation and improving its performance, and the willingness of the employee to share their experience and knowledge with others[14, 15]. Two distinct, but related, forms of civic virtue (CV) OCBs have been proposed – information gathering (CV- information) and influence exercising (CV-influence) [16]. While CV-information focuses on activities such as attendance at meetings and keeping up to date, CV-influence includes suggesting change within an organisation [16].

To the authors' knowledge, there has been no research examining OCBs within the HTA process but it may be that this model, and the associated research, provides a basis for understanding the behaviour – and how to

promote it. It is important that the mechanisms for this behaviour be understood within a HTA context, where clinicians include world leaders within their fields and therefore their involvement in medicine review processes is not just desirable but necessary. To this end an exploratory, qualitative evaluation was undertaken to examine why the clinical experts engaged and supported the medicine review process.

METHODS

Ethical Approval

The project was a service evaluation and therefore did not require University of Strathclyde ethical approval [17, 18]. Additionally, NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (REC) in the UK was not required as the project is an opinion survey seeking the views of NHS staff on service delivery (as advised by the East of Scotland NHS Research Ethics Service).

Materials

A semi-structured interview schedule was developed through discussions within the multidisciplinary evaluation team (comprising pharmacists, social scientists, medical clinician, and information analyst) and the evaluation's steering group. It was designed to capture a wide range of experiences and areas of interest around the role of the clinical expert. The schedule was piloted with a clinical expert and amendments were made as necessary (this participant was not included in the final sample). See supporting information for the schedule.

Procedure

The SMC provided details of their clinical experts (n=450) and an email was sent alerting them to the evaluation and inviting them to take part through return email. Fifty-four (12%) responded positively to the request. A purposive sampling strategy was devised to retain the proportions of profession, specialty and

geography of the respondents (see Table 1). A total of 30 participants were selected as it was viewed that this would be sufficient for saturation of data (i.e. no new themes would emerge in subsequent interviews).

[insert Table 1 around here]

One-to-one interviews were conducted at each clinical expert's place of work during office hours over the period between October 2011 and March 2012. Participants read an information sheet detailing what the study would involve, that the interview data would be anonymised and their participation was entirely voluntary. All participants signed the consent form provided by the researcher. All interviews were conducted by EDC, lasted between 30 and 90 minutes, were recorded using a Dictaphone and transcribed verbatim. A framework analysis was applied to the data, allowing the analysis of main themes to be carried out on a large volume of data [19, 20]. RN and EDC coded the data, then met and examined their developed thematic framework and coded data; areas of disagreement were resolved through consensus. These codes were then organised in order to develop themes and sub-themes by EDC.

RESULTS

Participants

Of the 30 clinical experts who had agreed to take part, three dropped out of the study prior to commencement of the interviews. The remaining 27 participants ranged in age from 32 to 63 years (median = 48, IQR= 46-53). A third of the sample were female and participants had been clinical experts for between 6 months to 10 years (median= 5, IQR= 3-7), and had given advice on between 2 and 60 medicines (median= 5, IQR= 3-10). Two participants had previously been members of the SMC. Participants represented 16 different medical/surgical specialties: oncology/haematology (n=6), anaesthetics (n=3), genitourinary /obstetrics and gynaecology (n=2), neurology (n =2), psychiatry/mental health (n=2), infectious diseases (n=2) and one

representative each from paediatrics, cardiology, orthopaedics, general medicine, rheumatology, endocrinology, biochemistry, ophthalmology, nephrology and liver transplant/surgical.

Data Analysis

Nine randomly selected interviews were read by two researchers who worked independently to derive frameworks of descriptive themes. These researchers then met and compared frameworks; disagreements were resolved through discussion. The remaining 18 interviews were coded and relevant quotes were selected and placed into the framework table and validated by a third researcher; additional quotes were added through discussion. This validated framework was summarised for the subsequent thematic analysis.

The thematic analysis identified three distinct themes related to why the clinical experts participate in the medicine review process: (1) recruitment; (2) flexibility of procedure; and (3) healthcare systems. Sub themes within these themes are explored and quotes are used to accompany these. Hesitations have been removed and, on occasion, words contained in parentheses have been added to clarify meaning or disguise any identifying information. Text that has been removed is represented by ellipses. Accompanying each quote, in brackets, are the participant's professional title and clinical expert experience. In general, the themes were expressed in the majority of the interviews unless stated otherwise. The supporting quotes are presented in Figure 1.

[Insert Figure 1 around here]

Theme 1: Recruitment

Only one clinical expert reported actively volunteering for the role. Many clinical experts were not entirely sure how they had assumed the role as clinical expert, only that they were approached. Two types of explanations for recruitment were identified: external justifications (recruited or nominated by others) and internal factors (recruited as a result of clinical experience). Both patterns of justification suggested that being

considered an expert in a field – either by one's own opinion or through the nomination of others – may be crucial in engaging the help of the clinical experts.

External Justification

Most participants reported being approached by SMC to become a clinical expert and either suspected or knew they had been nominated by colleagues, or identified through various committees they had been involved in (Quotation 1). In these cases, participants were often not fully aware of who had nominated them, and they often assumed that they were identified through these channels, with some even stating that they were never 'formally appointed' and had been involved almost by default (Quotation 2).

Internal Justification

Some participants reported that they had been recruited as clinical experts due to their level of involvement and expertise in their specialist field rather than referring to a nominator (Quotation 3).

Theme 2: Flexibility

Flexibility in Response Style

The way that clinical experts approached providing their advice on new medicines varied. Some experts felt that extra reading was required before giving advice (Quotation 4) whereas others felt that, as an "expert", their opinion should be informed enough to provide an appropriate and extensive answer. Additionally, the SMC was reported to give limited guidance regarding the length/focus of responses. This promoted the experts' autonomy, allowing their response style to vary depending on the individual clinician (Quotation 5). However, some clinicians voiced a preference for the SMC to provide them with guidance on the length/focus of response, and feeling confused around how extensively their answers should be researched (Quotation 6). Some participants did identify that there was probably a good reason behind not guiding or influencing clinical experts responses, as the SMC would be looking for an individual clinician's view rather than one influenced by external factors such as other expert advice. Many observed that the SMC did ask additional questions if their

answers had been lacking somehow, and assumed that if they didn't hear otherwise from the SMC and they were asked to provide advice again that they must be fulfilling their role adequately as an advice-provider.

Flexibility of Engagement Style

Many participants expressed that, although they felt more informed about SMC process since becoming a clinical expert, they still lacked knowledge around what the whole process involved, where they fitted into the process and what contribution their advice actually made to the final decision (Quotation 7). Although some were comfortable with the remote engagement style, many felt that their need to be fully involved and engaged with the SMC would be fulfilled if they were provided with more information and two-way feedback on the full extent of the role clinical experts were expected to play.

All participants reported being contacted via email whenever SMC requested their advice, with only a few speaking to an SMC staff member over the phone (this kind of interaction was usually initiated by the clinical expert). The advantage of emails was that they could be stored and responded to when convenient (Quotation 8) but some clinical experts expressed that they would appreciate more direct communication from the SMC, with the possibility for more involved engagement (Quotation 9). Little feedback was received by the clinical experts on the advice that they provided or information on the decision made by the SMC. Participants indicated that they usually became aware of the SMC decision through other routes (Quotation 10).

Flexibility of Response Time

Clinical experts reported that providing advice could be limited, and in some cases not possible, due to time restrictions. Participants also reported that SMC were very accommodating when time was an issue, and would often negotiate a more suitable date by which to provide their advice. This flexible 'no-pressure' approach may be attractive to busy experts, and thus motivate them to continue involvement with the SMC (Quotation 11). Some participants reported suggesting other colleagues to the SMC in the event that they could not provide advice within the timelines or considered that another person may be more appropriate.

Flexibility in what motivates a clinical expert

When asked what the benefits were of being a clinical expert, participants reported personal, internal and external motivators for responding to requests for advice. One important set of benefits mentioned were the personal development and learning opportunities associated with the role (Quotation 12). Responses ranged from participants finding it "interesting" and beneficial in keeping up-to-date on a scientific and clinical level; to others stating that it was important in alerting them to potential new medicines becoming available. Others felt a sense of personal satisfaction and prestige associated with the role. Many reported that it was rewarding to be recognised as an expert, by the SMC and by their peers, and to feel that they were one of the best informed in their particular field (Quotation 13). Some reported feeling more informed about the SMC in general, and feeling informed not only brought a sense of satisfaction, but being privy to the new medicines review process gave some participants confidence that the process was transparent and fair. Participants also reported the benefits of being able to see the impact of their advice when it was reflected in SMC decisions and guidance. The opportunity to influence SMC decisions was reported by many participants as a benefit of responding to requests for advice. Some saw it as a chance to impact upon prescribing behaviours and practice at a national level, which in turn made them feel part of national decision making in addition to their local NHS Board role (Quotation 14). These personal, internal and external motivators all provide insight as to why clinical experts volunteer their time to the SMC.

Theme 3: Healthcare Systems

The profile of the SMC within NHS Scotland

The relevance of the SMC's decisions to the clinicians' professional roles was recognised and overall the SMC was viewed positively. When asked their opinions of the SMC and why participants volunteered their time for them, the general consensus was that the organisation was valued (Quotation 15). Many reported trusting the SMC, having confidence in them and believing that they operated in a useful and fair manner, improving year upon year. Many also reported the benefits of the organisation's speed in making decisions, and praised their ability to provide clear and concise advice for clinicians (Quotation 16). The SMC was seen as approachable, and clinical experts felt valued in their role and praised the SMC for consulting clinicians whose prescribing practices would be directly affected by the outcome of the medicine review process (Quotation 17).

The relevance of the SMC within professional Role

Many participants reported seeing the relevance of being a clinical expert to their current professional role and volunteering as a clinical expert was a natural progression (Quotation 18). For some, being a clinical expert fell under the realm of professional activities expected of them as clinicians. Others also saw contributing to SMC processes as part of their continuing professional development (CPD) which all clinicians are required to record (Quotation 19). Engaging with the SMC as a clinical expert, therefore, provided some personal professional opportunities. Furthermore, some reported that being a clinical expert made them more aware of SMC guidance and more likely therefore to adhere to it. Additionally, participants commented on how being a clinical expert supported the clinician's role of helping and representing patients (Quotation 20). Some also saw being an expert advisor to the SMC as an opportunity to be more privy to information about new medicines, and this was important in managing patient care and expectations more effectively (Quotation 21).

DISCUSSION

The importance of engaging clinical experts in the HTA process is well recognised internationally[1, 7, 8, 10] but we found no published evidence on why experts engage and how this can be sustained and improved, particularly in an increasingly intensified clinical practice environment. This study identified three key themes that underpin why clinicians volunteer their time to HTA agencies: recruitment; flexibility of the procedures; and, the profile and relevance of the SMC within the health care system.

The current study's findings resonate with some of the OCB literature. Firstly, taking part in HTA was rewarding to the expert, although the exact reward depended on the individual. This is in line with literature reporting that helping behaviours, such as those seen with OCBs, are associated with positive consequences such as self-development or feelings of well-being [21]. Rewards such as seeing the results of their advice and the national impact suggest that clinical experts see the meaningfulness of their contribution. An employee's perception of their work as being significant has been positively linked to civic virtue behaviour which aims to change the way of working within an organisation (CV-influence)[16].Secondly, some clinicians viewed this role as an extension to their professional role and that they had a moral responsibility to their patients to

engage in this process. Expressions of OCBs are not always seen by employees as being discretionary [22] and moral obligations are thought to be consistent with OCBs [12]. Thirdly, the clinical experts appeared positive about SMC, and by association the NHS. Employees' perception of their organisation as being fair was an important determinant for OCBs [23], while commitment to the organisation was seen to predict civic virtue behaviours such as keeping up to date (CV-information) [16].

How an HTA agency engages their clinical experts is therefore likely to underpin experts' level of commitment to the HTA process. The flexibility offered by the SMC, such as with response style and timescales, may decrease obstacles to the clinicians' involvement in the HTA process. A The SMC engaged directly with the clinical experts and provided flexibility in response style and time, which were both highly valued by the experts. However, the clinical experts voiced that they would welcome increased two-way feedback on their input and the final decision made by the SMC. An investigation undertaken by an HTA organisation in the USA found that a common complaint among stakeholders was the lack of response to written comments submitted [10].

Outwith new medicines assessment, the wider clinical guideline development community – for example SIGN and NICE – recognise the importance of expert healthcare provider engagement[24, 25]. However, there remains limited evidence on why they engage and how this is sustained. Consideration of the OCB framework could support the wider engagement of expert clinicians across the HTA portfolio.

Study Strengths and Limitations

Participants self-selected into the study, which might imply that these experts were not representative of the group as a whole. It must be recognized that the motivations to reply to the recruitment email may be similar to those that drive involvement with the SMC and the experts who did not reply may represent a distinct group with differing views of SMC engagement. However, the experts interviewed were a heterogeneous sample from sixteen different specialties with a broad range of experiences in the role. It is recognized that by choosing to retain the geographical distribution of our original sample, we "lost" potential participants from three additional specialties (respiratory, prescribing support and colorectal). Motivations within clinicians who work in different clinical specialities may be more different than the motivations between NHS board

312 employees, although there was agreement across the specialties included in our sample. Clinical experts who
313 no longer gave advice, and their reasons for this were not included in this sample, but it would be important
314 for further exploration to involve such experts.
315
316 The issue of generalisability within qualitative research is an important one. For exploratory analysis such as
317 this, interviews give insight to the issues most relevant to the group being interviewed. However, the themes
318 derived from the data reflected the fact that there were many commonalities in their experiences with being a
319 clinical expert, and the lack of new emerging themes as the interviews progressed over time suggested that
320 saturation was reached (i.e. further interviews would not have resulted in additional themes). The extent to
321 which these findings are generalisable between countries is as yet poorly understood – although the OCB
322 literature suggests that cultural differences, for example between collectivist and individualist cultures, are
323 important within organisations [12]- and would benefit from further research.

324 **Future Directions**

325 Evidence suggests that organisations can improve their performance by encouraging OCBs[26].This project has
326 revealed the importance of autonomy, flexibility and awareness of the relevance of work to the national
327 agenda in explaining why clinical experts take part in the medicine review process. Balancing this with a call
328 from clinical experts for increased engagement (guidance on their role and feedback on their inputs) poses
329 challenges for any HTA; there is a balance to be struck between potential improved quality and
330 standardisation of responses through more directive guidance from HTAs and the potential perception, real or
331 not, of increased workload and reduced flexibility impacting on expert retention. Examining future
332 engagement enhancement initiatives through the lens of the OCB literature is a first step in understanding
333 how OCBs can be contextualised within healthcare as an enabler to capitalise on clinicians' expertise.

334 Further research should focus on how to maximise clinical expertise in vital health systems locally, nationally
335 and internationally through a growing understanding of OCB within these different healthcare settings. The
336 result will be the development of an evidence base on how HTAs may best engage this important stakeholder
337 group in their decision making processes.

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COMPETING INTERESTS STATEMENT

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: RN and EDC were funded through a grant from Health Improvement Scotland; JWD receives the financial support of NHS Research Scotland, through NHS Lothian; and SH is currently employed by the Scottish Medicines Consortium but was employed at NHS National Services Scotland, Public Health Intelligence during the study period. SMcT and MB have nothing to declare.

REFERENCES

1. Sorenson, C., Drummond, M., Kanavos, P. (2008) Ensuring value for money in health care. The role of health technology assessment in the European Union. http://www.ispor.org/congresses/prague1110/documents/PlenaryII-Role-of-HTA-in-the-EU.pdf (accessed 2nd July, 2014).
2. Taylor, R., Taylor, R. (2009) What is health technology assessment? . http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/What_is_health_tech.pdf (accessed 2nd July, 2014).
3. Velasco-Garrido, M., Busse, R. (2005) Health technology assessment: an introduction to objectives, role of evidence and structure in Europe. . http://www.euro.who.int/__data/assets/pdf_file/0018/90432/E87866.pdf (accessed 2nd July, 2014).
4. Moharra, M., Kubesch, N., Estrada, M., Parada, T., Cortés, M., Espallargues, M. M. (2008) EUnetHTA project. Survey report on HTA organisations. http://eunethta.fedimbo.belgium.be/sites/5026.fedimbo.belgium.be/files/Survey%20report%20on%20HTA%20organisations.pdf (accessed 2nd July, 2014).
5. Banta, D., Kristensen, F. B., Jonsson, E. (2009) A history of health technology assessment at the European level. International Journal of Technology Assessment in Health Care, 25,68-73.
6. Gulacsi, L., Rotar, A. M., Niewada, M., Loblova, O., Rencz, F., Petrova, G., Boncz, I., Klazinga, N. S. (2014) Health technology assessment in Poland, the Czech Republic, Hungary, Romania and Bulgaria. The European journal of health economics : HEPAC : health economics in prevention and care, 15 Suppl 1,13-25.
7. Health Information and Quality Authority. (2014) Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland. http://www.hiqa.ie/publications/guidelines-stakeholder-engagement-health-technology-assessment-ireland (accessed 2nd July, 2014).
8. Stephens, J., Handke, B., Doshi, J. (2012) International survey of methods used in health technology assessment (HTA): does practice meet the principles proposed for good research? Comparative Effectiveness Research, 2,29-44.
9. Pinson, N., Thielke, A., King, V. (2011) Health Technology Assessment. Rapid Review. . http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Health-Technology-Assessment_Public_RR_Final_08_18_2011.pdf (accessed 2nd July, 2014).
10. Curtis, P., Gordon, C., Slaughter-Mason, S., Thielke, A. (2012) Washington State Health Technology Assessment Program: Stakeholder Engagement Project http://www.hca.wa.gov/hta/documents/stakeholder_engagement_project_report_final_part_two.pdf (accessed 2nd July, 2014).
11. Scottish Medicines Consortium. (2014) Clinical Experts. https://www.scottishmedicines.org.uk/Submission_Process/Submission_Guidance_and_Templates_for_Industry/Clinical_Experts (accessed 9th July, 2014).
12. Organ, D. W., Podsakoff, P. M., MacKenzie, S. B. (2006) Organizational Citizenship Behavior: Its Nature, Antecedents, and Consequences. Thousand Oaks, California: Sage Publications, Inc.
13. Hoffman, B. J., Blair, C. A., Meriac, J. P., Woehr, D. J. (2007) Expanding the criterion domain? A quantitative review of the OCB literature. Journal of Applied Psychology, 92(2),555-66.
14. Podsakoff, P. M., MacKenzie, S. B., Paine, J. B., Bachrach, D. G. (2000) Organizational citizenship behaviors: A critical review of the theoretical and empirical literature and suggestions for future research. Journal of Management, 26(3),513-63.
15. Konovsky, M. A., Organ, D. W. (1996) Dispositional and contextual determinants of organizational citizenship behavior. Journal of Organizational Behavior, 17(3),253-66.
16. Graham, J., Van Dyne, L. (2006) Gathering Information and Exercising Influence: Two Forms of Civic Virtue Organizational Citizenship Behavior. Employee Responsibilities and Rights Journal 18,89-109.
17. University of Strathclyde Ethics Committee. (2008) Annual Report to University Management Committee for 2007/08. In.

18. University of Strathclyde. (2009) Code of practice on investigations involving human beings. In.
19. Ritchie, J., Spencer, L., O'Connor, W. (2003) Carrying Out Qualitative Analysis. In Qualitative Research Practice: A Guide for Social Science Students and Researchers (eds. J. Ritchie, J. Lewis), London: Sage Publications Ltd.
20. Pope, C., Ziebland, S., Mays, N. (2000) Qualitative research in health care - Analysing qualitative data (Reprinted from Qualitative Research in Health Care). British Medical Journal, 320(7227),114-6.
21. Spitzmuller, M., Van Dyne, L. (2013) Proactive and reactive helping: Contrasting the positive consequences of different forms of helping. Journal of Organizational Behavior, 34(4),560-80.
22. Morrison, E. W. (1994) Role Definitions and Organizational Citizenship Behavior: The Importance of the Employee's Perspective. The Academy of Management Journal, 37(6),1543-67.
23. Jex, S. M., Britt, T. W. (2008) Organizational psychology : a scientist-practitioner approach In, pp. 95-130, Hoboken, N.J. : J. Wiley & Sons, Inc. .
24. Scottish Intercollegiate Guidelines NetworK. (2014) SIGN 50: A guideline developer's handbook. http://www.sign.ac.uk/pdf/sign50.pdf (accessed 15th December, 2014).
25. National Institute for Health and Care Excellence. (2012) How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS. http://www.nice.org.uk/article/pmg6f/chapter/about-this-document (accessed 15th December, 2014).
26. Podsakoff, N. P., Whiting, S. W., Podsakoff, P. M., Blume, B. D. (2009) Individual- and organizational-level consequences of organizational citizenship behaviors: A meta-analysis. The Journal of applied psychology, 94(1),122-41.
27. SMC Evalation Team. (2012) Scottish Medicines Consortium Evaluation Programme: Final Report, December 2012. In (ed. S. M. Consortium): NHS Scotland.
28. Bennie, M., Corcoran, E., Dear, J., Hems, S., McTaggart, S., Newham, R., Norris, V., Waugh, C. (2013) An investigation of the horizon scanning approach used for new medicines in the Scottish National Health Service. In 11th EACPT Congress, Geneva, Switzerland.
29. SMC Evalation Team. (2013) An assessment of the accuracy of horizon scanning predictions of medicine use in the the Scottish National Health Service. In 11th European Association for Clinical Pharmacology and Therapeutics, Geneva, Switzerland.

TABLE LEGEND

Table 1. Comparison of the medical specialty of SMC experts who agreed to be involved in the study with those who were finally recruited.

Medical Specialty	All Respondents Total (%)	Participants Total (%)	Difference (%)
Oncology/Haematology	12 (22.2%)	6 (22.2%)	0
Anaesthetics	8 (14.8%)	3 (11.1%)	-3.7%
Genitourinary /OBGYN	6 (11.1%)	2 (7.4%)	-3.7%
Neurology	4 (7.4%)	2 (7.4%)	0
Psychiatry/Mental Health	4 (7.4%)	2 (7.4%)	0
Infectious Diseases	2 (3.7%)	2 (7.4%)	+3.7%
Paediatrics	1 (1.9%)	1 (3.7%)	+1.8%
Cardiology	1 (1.9%)	1 (3.7%)	+1.8%
Orthopaedics	1 (1.9%)	1 (3.7%)	+1.8%
General Medicine	4 (7.4%)	1 (3.7%)	-3.7%
Rheumatology	1 (1.9%)	1 (3.7)	+1.8%
Endocrinology	1 (1.9%)	1 (3.7)	+1.8%
Biochemistry	1 (1.9%)	1 (3.7)	+1.8%
Ophthalmology	2 (3.7%)	1 (3.7%)	0
Nephrology	1 (1.9%)	1 (3.7)	+1.8%
Liver Transplant/Surgery	1 (1.9%)	1 (3.7%)	+1.8%
Respiratory	2 (3.7%)	0	-3.7%
Prescribing Support	1 (1.9%)	0	-1.9%
Colorectal	1 (1.9%)	0	-1.9%

FIGURE LEGEND

Figure 1: Themes and quotations arising from clinical expert interviews

Theme 1: Recruitment

External Justification

1. *I think one of my colleagues must have nominated me. Because I just got an email so I suspect because the people I share an office with … I presume it was [my colleague] that nominated me* (Clinical Effectiveness Pharmacist, clinical expert for 4 years)

2. *I think I just got emailed ... they send out the email and say, "Do you know anything about this drug? Do you feel confident in giving us an opinion on this drug?" …but there's never been an actual formal appointment* (Consultant, clinical expert for 7 years)

Internal Justification

3. *I've worked in [specialty] for 15/20 years now since-since qualifying, I've been involved since 1990* (Consultant, clinical expert for 2 years)

Theme 2: Flexibility

Flexibility in Response Style

4. *It's worth just checking what the current clinical guidelines are and saying well, this medicine fits in to that gap, or alternatively, there is no place for this particular drug... So it involves some reading around the subject* (Consultant, clinical expert for 10 years)
5. *It does depend on how much work you feel you've to put into it personally 'cause if you feel you've got to go off and do a literature search on it, but that's never the approach I've taken.* (Consultant, clinical expert for 3 years)
6. *I answer the email in a particular way but I don't know if what I'm doing is one hundred per cent correct... so there is I suppose a lack of two-way feedback* (Consultant, clinical expert for 7 years)

Flexibility of Engagement Style

7. *Interviewer: So you don't know anything that happens [with your advice]?*
   Clinical expert: Not a clue... [It's] a bit like leaving an exam without a mark (Consultant, clinical expert for 7 years)
8. *I'm quite happy to be contacted in the way that I'm contacted and email seems quite convenient really* (Consultant, clinical expert for 7 years)
9. *I've certainly never been to anything ...they are a little bit distant.* (Consultant, clinical expert for 10 years)
10. *It would be useful for them to feedback the guidance once it's public ...directly to us rather than having to wait to hear* (Consultant, clinical expert for 3 years)

Flexibility of Response Time

11. *I've missed it, because I was away on holiday … so I've just emailed back and said, 'I'm sorry, I was away, I've missed the date', so they've then emailed back and said, 'Well, can you send your response anyway?'* (Consultant, clinical expert for 6 years)

Flexibility in what motivates a clinical expert

12. *It actually makes me think that, you know, there are new drugs out there. It makes me do the work and trawl through the literature … it keeps you in tune of what's coming out* (Consultant, clinical expert for 7 years)
13. *I'm happy to do it... everyone wants to be an expert, don't they? You know, that's like a pat on the head.* (Consultant, clinical expert for 6 years)
14. *It should give me a way to influence their decisions* (Consultant, clinical expert for 10 years)

Theme 3: NHS Systems

The profile of SMC within NHS Scotland

15. *I think it's quite nice to have a Scottish organisation taking advice from Scottish experts and producing its own opinions, and I do think it's valuable.*(Consultant, clinical expert for 5 years)
16. *I think it's excellent and the summaries they provide, the assessment of products are very clear, comprehensive - they give good guidance, they're timely.*(Principal Pharmacist, clinical expert for 5 years)
17. *I suppose benefits to the services that I see is it's very useful that they get real life feedback on what happens in practice rather than just from reading the papers that the company have submitted or whatever.*(Clinical Effectiveness Pharmacist, clinical expert for 4 years)

The relevance of SMC within Job Role

18. *I think this is, in a way, part of our job… we all have a professional responsibility to practice cost-effectively, and also to advise colleagues, because, you know, as specialists in the field, we then need to advise, for example, general practitioners.* (Consultant, clinical expert for 1 year)
19. *I obviously take part in continual professional development, and I do read articles/ literature …I think you focus more if you're being asked to give an expert opinion because you realise there's a responsibility to this*(Consultant, clinical expert for 1 year)
20. *It's a little bit altruistic that you do it for the greater good...if you become a senior consultant or if you become an expert in the field, it's part of the payback* (Consultant, clinical expert for 10 years)

21. *Engagement with the SMC allows me to feel that I'm contributing to the availability of exciting new [specialty] drugs for my patients. That's what it's all about (Medical Practitioner, clinical expert for 5 years)*