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**Assessing the quality of health technology registers for national guidance
development**

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Abstract

Background

The National Institute of Health and Care Excellence makes use of registers to collect data for technologies that require more evidence to inform future decision-making. This is particularly so for the Interventional Procedures Programme, which since 2003 has produced guidance for procedures that are typically not well established, meaning that named registers are often recommended for future data collection.

Methods

We constructed a questionnaire based on quality standards for recommended registers defined by the Interventional Procedures Programme. All guidance from 2003 to 2016 were reviewed to identify recommended registers and compile a list of corresponding registries. We made a maximum of four attempts to contact each register. Each register was scored on seven quality standards: accessibility, responsiveness, data publication, data coverage, data validity, independent oversight and data protection, with a maximum of 14 points.

Results

We obtained responses from 17 out of 24 eligible registries, a response rate of 70.8%. The mean total score was 8.5 (standard deviation 2.9, range 4 to 14). Overall, the quality of recommended registers was disappointing, with a split between large registries that scored highly across all standards and smaller registries that scored poorly.

Conclusion

This the first study to our knowledge to assess the quality of registers recommended by health technology assessment agencies. Only a limited number of registers were mature enough to deliver evidence of sufficiently high quality to inform funding decisions. A standardised quality assessment tool is needed to evaluate registers before their recommendation for observational data gathering by decision-making bodies.

Key words

Registry, register, data quality, health technology assessment, quality improvement

Introduction

There is increasing pressure on health service funders around the world to accelerate the review process for new technologies in order to give patients early access to potentially transformative technologies (1,2). All proposals for early access require the support of ongoing safety and efficacy monitoring through observational data gathered after new technologies are available on the market. This can identify clinically important adverse effects that are less frequent in research than real world conditions, as well as assess the effectiveness of apparently efficacious technologies (3).

Studies based on routinely collected health service data could be an efficient way of assessing effectiveness, but methodological challenges include appropriate identification of comparator data and insufficiency of data for case mix adjustment (4). There is therefore a place for well conducted observational data gathering through registers. Regulators have been concerned about the quality of evidence gathered in this way, however, leading to the development of quality standards to support the process (5,6).

As part of its health technology assessment programs, the National Institute of Health and Care Excellence (NICE) has often recommended that registers collect data for technologies that require more evidence to allow and inform future decision-making. This has been particularly the case for the Interventional Procedures (IP) Programme, which provides guidance for UK health professionals on the safety and efficacy of new clinical procedures that involve making a cut through the skin, using instruments to enter the body (e.g. an endoscope) or equipment which uses energy

sources (e.g. ultrasound) to diagnose or treat patients. These procedures are typically not well established, meaning that there is often a paucity of evidence on which to make recommendations. Since its establishment in 2003, IP guidance has frequently recommended the collection of further data in specific named registers, with the intention of enriching the evidence base for the technology in order to inform future reviews of the guidance.

The most recent operational manual for the IP programme specifies four standards that should be met by any recommended register (see Table 1) (7). Many of the registers recommended by NICE were assessed prospectively against the standards when guidance was written, but a retrospective audit of the registers has not been undertaken to date. We undertook a survey of registers recommended by the NICE IP Programme against these quality standards to a) assess the fitness for purpose of recommended registers, and b) assess the quality of registers used in the NICE IP program since 2003.

<< Table 1 around here >>

Methods

Questionnaire development

We constructed a questionnaire based on the four IP quality standards as well as an additional question on data publication (see supplementary file 1). This was piloted by the IP team as part of its ongoing work to develop procedure guidance.

Data collection

All IP guidance recommendations from 2003 to 2016 were reviewed to identify where recommendations for data collection through registers had been made and compile a list of corresponding registries. We made a maximum of four attempts to contact each register

: an initial email; a reminder email after 4 weeks if no response; a "firm reminder" email sent from the Director of the IP team if no response after 8 weeks; and as a final measure emails sent to other contacts within the register asking them to fill in the survey if no response after 10 weeks. Registries for registers recommended in multiple pieces of guidance were only asked to send one response.

Quality scoring

Each register was scored independently by the authors on seven quality standards: accessibility, responsiveness, data publication, data coverage, data validity, independent oversight and data protection. Each standard could score zero, one or two, giving a maximum of 14 points. The standards and scoring criteria are described in Table 2. All registries were scored on accessibility and responsiveness, whereas only responding registries were scored on the other five standards. Objective evidence of data publication provided by the register was scored by one

author. As data coverage, data validity, independent oversight and data protection were more subjective, three authors independently scored all survey responses for these four standards. A two-way mixed-effect average-measures absolute-agreement intraclass coefficient was calculated for each of these standards (8). For responding registries, the score for these standards was averaged and added to the scores for the other three standards to produce a total score for each register.

<< Table 2 around here >>

RESULTS

In total, 28 registers have been recommended in IP guidance since 2003 (see supplementary file 2). Four of these registers were excluded from the survey (see Figure 1 for flow of responses and reasons for exclusion). We obtained full responses from 17 of the 24 eligible registries, a response rate of 70.8%.

<< Figure 1 around here >>

For responding registries, the mean total score was 8.5 (standard deviation 2.9, range 4 to 14). Table 3 outlines the number of registries receiving scores of zero, one or two for each standard. The intra-class coefficients for the multi-rated standards show a high inter-rater reliability for data coverage, but lower (although still significant) reliability for the other three standards.

<< Table 3 around here >>

With regard to accessibility, one in four registries did not have any contact details available on the internet. In contrast, a third had online data easily accessible for secondary analysis. Websites generally did not provide sufficient evidence to allow the standards to be assessed without contacting a register representative. As for responsiveness, nearly a third of registers responded readily to our request for information. Nearly half, however, required follow-up with alternative contacts at the register or did not respond at all. The large international registries (for example, the International Registry of the Extracorporeal Life Support Organization (ELSO)) were

particularly hard to communicate with because it took time to get through to a member of staff that could answer questions on quality.

For those registers where their responses allowed quality to be assessed, scores broadly tended to be bimodal with either high or low scores across the range of quality standards. For example, nearly half of registers had not published any data at all compared to over 40% who had (often numerous) peer-reviewed publications. Similarly, over two fifths provided ample evidence that they were meeting data protection principles, while nearly the same proportion provided no or scant evidence. The majority of registers are managed by an independent steering group, but over half were not able to confirm that coverage of the data is routinely monitored and the data validated. The lowest agreement between raters was seen on the standard concerning the clinical relevancy of collected data, with registries rarely stating explicitly their process for making modifications to registers.

DISCUSSION

We undertook a survey of all registers recommended in NICE IP guidance since 2003. We found the majority of registers inaccessible with relatively little information about the standard of data available from the register's website. Even when specifically asked for a response, a number of registries failed to provide any information that allowed an objective assessment against pre-defined quality standards. Amongst registers from whom information was received, standards relating to governance were more often met than those relating to data quality.

This is the first study to our knowledge assessing the quality of registers recommended by health technology agencies specifically to support decision making. Overall, the quality of recommended registers was disappointing, with a split between large registries that scored highly across all standards and smaller registries that scored poorly. Registries are often willing to collaborate with regulatory and HTA bodies to help with providing relevant "real world" data (9). However, we have shown that only a limited number of registers recommended by NICE are mature enough to deliver evidence of sufficiently high quality to inform funding decisions. In order to ensure HTA bodies are only utilising registers that are fit-for-purpose, it is important to be able to distinguish between those registries capable of providing high-quality observational data and those that require more support to be able to do so.

Several authors have reviewed the important characteristics of a register that are required for it to deliver high quality data (10),(11). Desirable qualities that have been described include strategic national collaborations amongst key stakeholders; an

independent steering committee to lead and oversee the register; consensus meetings to agree register objectives, minimum dataset and data ownership; accessible data processing systems with training for users; data validation with specialist clinical support to question and feedback on data submitted. In order to evaluate whether a register should be recommended for observational data gathering, a standardised quality assessment tool that encompassed these characteristics would be useful. While some quality assessment tools already exist, including those developed by Parent, AHRQ and Eucomed, none of these have yet been become standard (12-14).

This work is useful in piloting methodology that can be developed in line with the needs of national initiatives to improve the validity and use of observational data in health technology assessment. We performed a comprehensive audit of recommended registers, supported by a rigorous process for scoring responses. We were constrained by the previously defined quality standards, which would have been more meaningful if a set of acceptable evidence were listed against which register submissions could be assessed. This was particularly a problem for the standard relating to data protection because respondents generally confirmed that all legal requirements relating to data protection and information governance are met but did not provide evidence.

In conclusion, this audit has shown that not all registers recommended by NICE's IP Programme to date are capable of producing high quality evidence for post-market surveillance of new technologies. A standardised quality assessment tool is needed to evaluate registers before their recommendation for observational data gathering

by decision-making bodies. This learning will be submitted to the EuneHTA Joint Action 3 Work Package 5 to inform the development of standards and tools to be used by the 78 partner organisations [weblink: <http://www.eunetha.eu/news/core-workpackages>].

Acknowledgements

The authors would like to thank all the register representatives who gave their time to fill in the survey.

Conflicts of interest

HP, KH and TM are all employees of NICE. KM was on placement (but not employed) at NICE while this work was undertaken. We, the authors, declare no other conflicts of interest.

Keypoints

- This the first study to assess the quality of registers recommended by health technology assessment agencies
- Overall, the quality of recommended registers was disappointing, with a split between large registries that scored highly across all standards and smaller registries that scored poorly.
- Only a limited number of registers recommended by NICE are mature enough to deliver evidence of sufficiently high quality to inform funding decisions.
- It is important for health technology assessment agencies to be able to distinguish between those registries capable of providing high-quality observational data and those that require more support to be able to do so.

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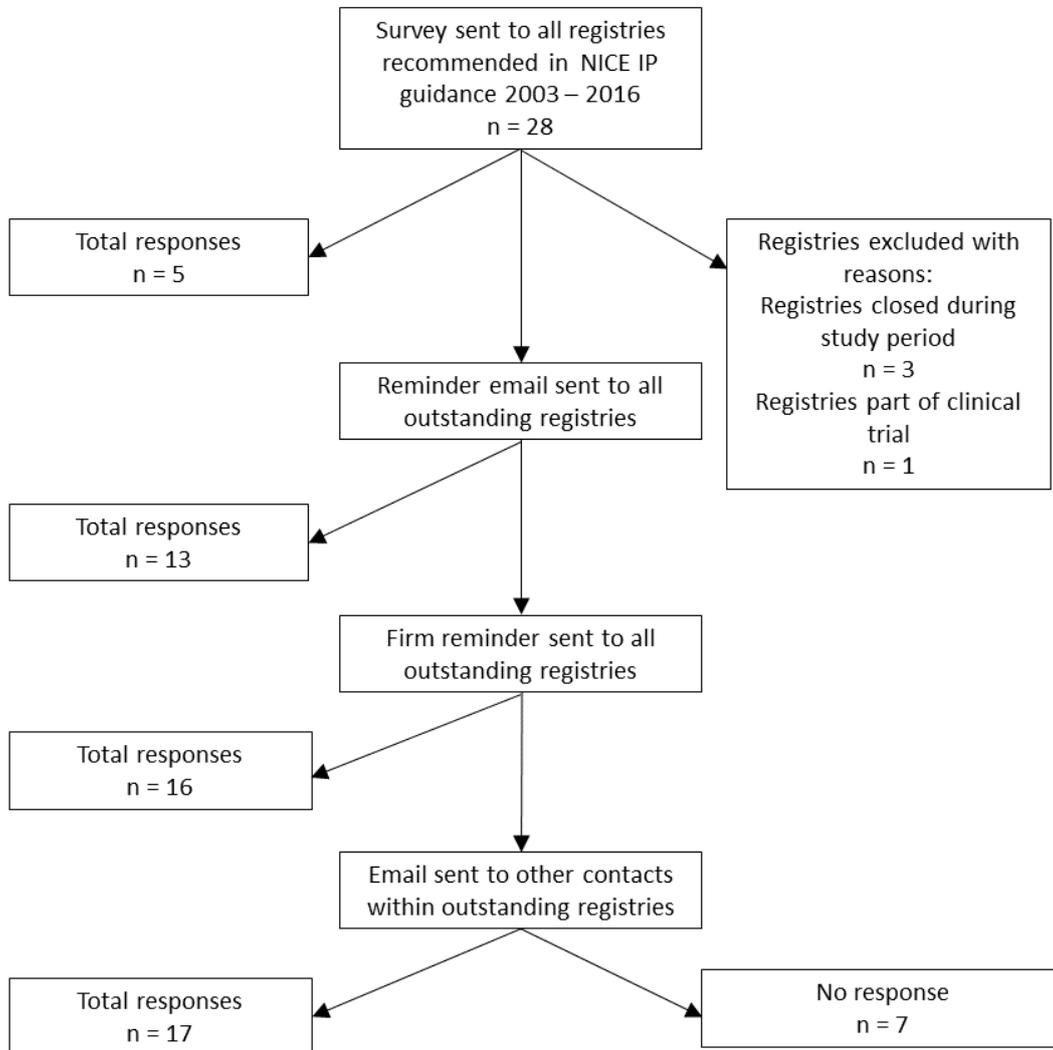
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Figures

Figure 1 Flow of responses



Tables

**Table 1 Quality standards for registers recommended by the
Interventional Procedures Programme**

Quality standard
All known procedures (all devices), without exception, are recorded in the database
The data recorded address relevant efficacy and safety outcomes and important patient characteristics
There is independent oversight of the register
The register complies with the data protection principles laid out in the UK Data Protection Act 1998 and any other relevant legislation.

Table 2 Quality standards and scoring criteria

Standard	Definition	Scoring criteria		
		0	1	2
Accessibility	Contact details and anonymised data for the register are available on the internet	No contact details for register on internet (i.e. no website or webpage)	Contact details available on internet	Contact details and data available for secondary analysis by third party
Responsiveness	Register responds promptly to requests for information	Chasing through other register contacts required before survey completed	Firm reminder required before survey completed	≤ 1 reminder email required before survey completed
Data publication	Data from the register on the interventional procedure has been published	No or not answered	Non-peer reviewed publication(s) e.g. annual report	Peer reviewed publication(s) with valid reference(s)
Data coverage	All known procedures, without exception, are recorded in the database	No or Yes without any further or incomplete information	Register has access to appropriate denominator data to assess data coverage	Validation has been carried out on database

Data validity	The data recorded address relevant efficacy and safety outcomes and important patient characteristics	Yes but no further information on how standard met	MHRA/NICE/professional representatives were involved in dataset design BUT NO process in place for making modifications to register	MHRA/NICE/professional representatives were involved in dataset design AND process in place for making modifications to register
Independent oversight	There is independent oversight of the register	No independent steering group or a commercial conflict of interest exists or incomplete information	Independent steering group and no commercial conflict of interest	Independent steering group and no commercial conflict of interest AND on national register OR explicit intent to publish
Data protection	The register complies with the data protection principles laid out in the UK Data Protection Act 1998 and any other relevant legislation	0-2 of below criteria met (evidence given for each)	3-6 of below criteria met (evidence given for each)	7-8 of below criteria met (evidence given for each)
		Data are: (i) used fairly and lawfully; (ii) used for limited, specifically stated purposes; (iii) used in a way that is adequate, relevant and not excessive; (iv) accurate; (v) kept for no longer than is absolutely necessary; (vi) handled according to people's data protection rights; (vii) kept safe and secure; (viii) not transferred outside the European Economic Area without adequate protection.		

Table 3 Registries' score by standard

Standard	Number of registries with score (%)			Intra-class coefficient
	0	1	2	
All eligible registries, one scorer				
Accessibility	6/24 (25.0%)	10/24 (41.7%)	8/24 (33.3%)	
Responsiveness	9/24 (37.5%)	8/24 (33.3%)	7/24 (29.2%)	
Only responding registries, one scorer				
Data publication	8/17 (47.1%)	2/17 (11.8%)	7/17 (41.2%)	
Only responding registries, three scorers (each score counted uniquely)				
Data coverage	16/51 (31.4%)	13/51 (25.5%)	22/51 (43.1%)	0.82 (95% CI = 0.59 to 0.93, F(16,32) = 6.1, p<0.001)
Data validity	12/51 (23.5%)	6/51 (11.8%)	33/51 (64.7%)	0.61 (95% CI = 0.14 to 0.84, F(16,32) = 2.6, p=0.011)
Independent oversight	7/51 (13.7%)	8/51 (15.7%)	36/51 (70.6%)	0.68 (95% CI = 0.27 to 0.88, F(16,32) = 3.1, p=0.004)
Data protection	22/51 (43.1%)	6/51 (11.8%)	23/51 (45.1%)	0.65 (95% CI = 0.23 to 0.86, F(16,32) = 3.4, p=0.001)

