BMJ Open How are declarations of interest working? A cross-sectional study in declarations of interest in healthcare practice in Scotland and England in 2020/2021

Margaret McCartney , ¹ Raphaella Bergeron Hartman, ¹ Harriet Feldman, ² Ronald MacDonald, ^{1,3} Frank Sullivan , ¹ C Heneghan, ² Calum McCutcheon ⁴

To cite: McCartney M, Bergeron Hartman R. Feldman H. et al. How are declarations of interest working? A cross-sectional study in declarations of interest in healthcare practice in Scotland and England in 2020/2021. BMJ Open 2022;12:e065365. doi:10.1136/ bmjopen-2022-065365

Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2022-065365).

Received 02 June 2022 Accepted 02 October 2022



@ Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹University of St Andrews. University of St Andrews Bute Medical School, St Andrews, UK ²University of Oxford, Oxford, UK ³University of Dundee School of Medicine, Dundee, UK ⁴Medical School, University of Glasgow, Glasgow, UK

Correspondence to

Dr Margaret McCartney; mm494@st-andrews.ac.uk

ABSTRACT

Objective To understand arrangements for healthcare organisations' declarations of staff interest in Scotland and England in the context of current recommendations.

Design Cross-sectional study of a random selection of National Health Service (NHS) hospital registers of interest by two independent observers in England, all NHS Boards in Scotland and a random selection of Clinical Commissioning Groups (CCGs) in England.

Setting NHS Trusts in England (NHSE), NHS Boards in Scotland, CCGs in England, and private healthcare organisations.

Participants Registers of declarations of interest published in a random sample of 67 of 217 NHS Trusts, a random sample of 15 CCGs of in England, registers held by all 14 NHS Scotland Boards and a purposeful selection of private hospitals/clinics in the UK.

Main outcome measures Adherence to NHSE guidelines on declarations of interests, and comparison in Scotland. Results 76% of registers published by Trusts did not routinely include all declaration of interest categories recommended by NHS England. In NHS Scotland only 14% of Boards published staff registers of interest. Of these employee registers (most obtained under Freedom of Information), 27% contained substantial retractions. In England, 96% of CCGs published a Gifts and Hospitality register, with 67% of CCG staff declaration templates and 53% of governor registers containing full standard NHS England declaration categories. Single organisations often held multiple registers lacking enough information to interpret them. Only 35% of NHS Trust registers were organised to enable searching. None of the private sector organisations studied published a comparable declarations of interest register.

Conclusion Despite efforts, the current system of declarations frequently lacks ability to meaningfully obtain complete healthcare professionals' declaration of interests.

INTRODUCTION

Declarations of interest (DOI) are commonly required by employers, journals, conferences, guideline and other committees. Financial

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ First study assessing the impact of 2016 National Health Service (NHS) guidance on declaring interests on practice in Trusts and Clinical Commissioning Groups
- ⇒ First study assessing current practice in NHS Scotland.
- ⇒ First study assessing current practice in private hospitals and clinics.
- ⇒ We were not resourced to research Wales or Northern Ireland.
- ⇒ We did not complete General Practice (GP) practice data due to (1) more data being available from Clinical Commissioning Groups than expected and (2) the pressures on GP practices during COVID-19, limiting ability to respond to information requests.
- ⇒ Staff information lacking from private hospitals and clinics may have been available if staff also worked in the NHS.

interests, for example, working as a consultant to a pharmaceutical or device company, or holding patents in a relevant area, are not the only concern. Other interests include loyalty to friends and family (eg, in recruiting for a job or commissioning a service), professional interests (eg, being part of a campaigning group for more resources in a particular area and lobbying for these) or political interests (eg, membership of a party, whose stated positions may conflict with a particular role). Other conflicts may be gifts and hospitality, where technology or device companies may pay for professionals to attend conferences or meetings. Free education may also be provided along with some hospitality (food and drink), though there are restrictions on the cost of gifts that can be given to professionals. These may all be judged to create a conflict in some situations.



Table 1 NHS England trust results

Number of trusts	Board registers available	Governers register available	Decision makers register available	•	Gifts and hospitality register available	If no separate gifts and hospitality register, included elsewhere?
67	53 (79%)	14: No 26: Yes N/A: 27	38: No 29: Yes	51: No 16: Yes	36: No 31: Yes	17/36: Yes 2: Partial 15/36: No
Percent available	79	35	43	23	46	28
Partial refers to som		ce).				

Conflicts of interest have the potential to adversely affect patient care in multiple ways. For example, financial conflicts have been found to be associated with potential bias in systematic reviews² and distorted outcomes from drug and device studies.³ Guidelines for use of opioids in non-cancer pain are prone to bias due to authors' conflicts of interests, now implicated in the opioid crisis.⁴ Pharmaceutically sponsored medical education, typically made free for healthcare professionals, is associated with more expensive, poorer quality prescribing.⁵

How to declare and manage conflicts has been a contested debate. Until the 1980s, declarations made by journal authors were haphazard and voluntary. 6 After a series of medical frauds and misconduct in the USA, the House Science and Technology Committee published 'Is Science for Sale? Conflicts of Interest vs the Public Interest'. The Committee heard how financial links between companies, research institutes and universities were a 'recipe for conflicts of interest' and how 'very few scientists would admit that the commercial associations have affected them personally'. Subsequently, medical organisations became more interested in requesting conflicts of interest from their contributors. In 1993, The International Committee of Medical Journal Editors wrote that authors must 'recognise and disclose financial and other conflicts of interest that might have biased their work. They should acknowledge in the manuscript all financial support for the work and other financial and personal connections to the work'. This was later formalised with explicit instructions for disclosure.

Debate resulted in a variety of 'Sunshine Acts' enacted between 2012 and 2018 in the USA, Australia and some European countries, ¹⁰ but notably not the UK. These Acts variously mandate public disclosure of healthcare professionals' affiliations with industry, either by the individuals, or by pharmaceutical or other companies. In 2016, Disclosure UK, a voluntary searchable website, was organised by the Association of the British Pharmaceutical Industry, containing disclosures to healthcare organisations, charities and individuals from pharmaceutical companies. ¹¹

In the UK, the dominant medical employer, and provider of healthcare, is the tax-funded National Health Service (NHS). The UK began an internal market healthcare system in the early 1990s. In the late 1990s Scotland, Wales and Northern Ireland gained devolved political

administrations, and subsequently organised their NHS differently. In England, multiple reorganisations have occurred in the administration of this internal market. A process of 'fundholding' enabled GPs to purchase community services for patients, which was followed by 'Clinical Commissioning Groups' (CCGs). These geographical groups, made up of mainly GPs, were charged with commissioning healthcare for the local area. This created an inherent conflict of interest, as by 2015, primary care clinicians were both able to commission and provide primary care services. Governance processes were developed as a way to manage this. 12 CCGs were replaced by Integrated Care Systems in mid 2022, who similarly commission services on a geographical basis. In England, NHS Trusts provide hospital, mental health and ambulance services, again organised geographically. These are public sector organisations, directed by a Board and accountable to NHS England. After health was devolved to the Scottish Government in 1999, legislation to end the internal market was enacted. There is no equivalent to CCGs in Scotland, as NHS Scotland Health Boards commission and deliver services. Fourteen regional NHS Boards in Scotland cover defined geographical areas and directly employ NHS staff, mainly in secondary care, with national health Boards similarly covering specialist areas such as NHS Education for Scotland. Health and Social Care Partnerships include general practices as well as social care services and are committees of NHS Scotland Boards.

In both 2005 and 2021 the UK Government rejected proposals for central, standardised registers of staff declared interest in favour of holding them at local level. ¹³ However, there was demonstrable poor practice in declarations published by English hospital employers in 2015–16 with much information missing or incomplete. ¹⁴ Scotland's Parliament rejected a public petition calling for a Sunshine Act in 2019. ¹⁵

In 2016, a review in NHS England recommended improvements in declarations for hospital employers and CCGs, issuing templates for defined staff groups to record interests (relevant shareholding and ownership interests, professional/personal financial/non-financial direct or indirect interests; actions to be taken in respect of a conflict) and instructions for completion of gifts and

Table 2 NHS England trust register analysis

Number of registers held by trusts	Published prior to 2020	Standard search/ declaration categories used?	Searchable?	Confirmatory negative declaration possible?	Quantified?	Explicit action noted?
162	No: 102 R: 11 UK: 2 Yes: 47	No: 123 Yes: 39	No: 105 ► A: 49 ► S: 8	No: 51 Yes: 98 C: 13	No: 120 Yes: 42	No: 136 Yes: 16 P: 10
Percentage	29	24	35	69	26	10

C, column dedicated to an affirmation of a negative declaration; P, partial, searchable either by alphabetical layout (A) or a search box (S); R, rolling (continuously updated; UK, unknown.

hospitality registers. These were intended to ensure consistent declarations, to be published 'in a prominent place' online, and be 'accessible and contain meaningful information'. Information could be exceptionally redacted when 'real risk of harm or is prohibited by law'. 16 CCGs received similar, statutory guidance regarding declarations in 2017.

Scotland has had no similar recent review. In requesting current national policies for staff to declare interests, we were asked to apply via a Freedom of Information request and advised that NHS Circular No 1989, 17 which applies to medical and non-medical staff, was still extant. This states that staff must notify their employer if they have a relationship with a current or likely future contractor, and 'establish and maintain registers both of the financial interests of any staff involved in purchasing/commercial policy and of any 'gifts or considerations' received by staff from any commercial sources.' A further circular in 1994 offers guidance for declarations for Board Members. 18 While NHS England recommends annual publication of relevant registers on a prominent place on their website, there is no equivalent national statement for NHS employees in Scotland. Declarations to employers in Scotland is therefore inferred to involve self judgement to declare conflicts, not interests. However, individual Board policy may state that staff interests should be declared and/or be open to public access.

Disclosure potentially allows a reader, to some extent, to make judgements on their relevance and potential impact.¹⁹ Some organisations have gone further, for example, Open Payments,²⁰ and Dollars for Docs²¹ have asked citizens to actively consider whether their healthcare provider is conflicted and encouraged searching for individual practitioner records. However, the Open Payments database in the USA does not appear to have changed physical behaviour or caused patients to use information from it. 22

Despite the ubiquity of requests for declarations, there are unresolved tensions, particularly purpose. This is reflected in the names given to disclosures required in situations 'where the impartiality of research may be compromised because the researcher stands to profit in

some way from the conclusions they draw'. For example, a disclosure of 'conflicts of interest' requires insight and judgement on when disclosure is applicable, as does a requirement to state 'dual commitments', 'competing interests' or 'conflicting loyalties'. Doctors recognise that other doctors, subject to gifts from industry, may be conflicted in their judgements, but tend to feel they themselves are immune to the same influences.²³ This suggests questionable insight, and infers that judgements over when an interest constitutes a conflict are best made by an independent observer. This would therefore support disclosures of 'interests' rather than 'conflicts', which reflects NHS England practice. This is in keeping with many professional regulators' expectation of transparency.²⁴ A lack of candour and openness in management of conflicts is described as a risk to professional trust and credibility by some medical organisations.²⁵ However the purpose of disclosure should not merely be transparency. This alone may come with unintended harms, such a presumption that transparency is management of a conflict, resulting in 'moral license'. 26 27 This is important, as disclosure could result in worse, not better practice. Some have argued that disclosure is a fallacy, as it cannot negate a conflict.²⁸ While this is true, and it would be better to have no conflicts, this is unrealistic, and disclosure will be required in the first stage of managing them.

The working assumption is therefore that disclosures of interest are necessary. However, there are a variety of people and organisations who may be expected to do this work and for different purposes, for example, patients (to make decisions about health choices), commissioners (to decide whether member of staff can take part in a decision) or clinicians (to decide how to judge a guideline). Disclosures should therefore contain enough information for others to interpret their meaning. While this requires further examination, we sought to examine what the current practice is: whether guidance to NHS England employers has resulted in registers of declarations compliant with guidance, what current declarations practice is within NHS Scotland, how healthcare professionals have responded to calls for their declarations and

BMJ Open: first published as 10.1136/bmjopen-2022-065365 on 4 November 2022. Downloaded from http://bmjopen.bmj.com/ on September 21, 2023 by guest. Protected by copyright

Table 3 NHS Scotland Board registers

NHS Scotland Boards	Boards with a public published board register of interests	Boards with a public published staff DOI register	Boards with a public published gifts and hospitality register	Boards with all NHSE standard categories included in public DOI registers	Boards with all NHSE standard categories included in gifts and hospitality registers	Boards with a substantive redaction from any register	Registers more than 18 months old
14	14	2/14	6/14	1/14	3/14	9/33	6/35
Percentage	100	14	43	7	21	27	17

Staff home address was not counted as a redaction.

DOI, declaration of interest.

whether this has resulted in interpretable information for lay or professional readers.

Study objective

In the UK, The Independent Medicines and Medical Devices Safety Review (2020), like the Health Select Committee before it (2005), recommended doctors make a statutory declaration of their interests on a central register. 29 30 This proposal has been rejected by government who instead continue to recommend locally made declarations. However it is uncertain whether these are fit for purpose in describing actual or potential conflicts of interest, and enable others to make an informed judgement on their relevance and potential effects. We therefore examined current practice of public DOI of hospitals in England and Scotland, and CCGs in England, along with a purposeful selection of private clinics and hospitals, which we do not believe have been previously examined in this way. Due to resource limitations we excluded Wales and Northern Ireland from our study. We judged declarations in NHS England, Scotland and the private sector against contemporary NHS guidance in England. We aimed to understand current practice in declaring interests in the UK by assessing the compliance of employers in publishing registers of interest as recommended by NHS England guidance, how employees have responded to these requests, and the organisational effectiveness of declarations of being available and containing enough information to interpret them.

METHODS

Patient and public involvement

This research is part of a wider suite of work into DOI, which has a patients/citizens panel.³¹ This project was suggested and discussed by and with members, who contributed in particular to what a meaningful DOI would include, and what private clinics and hospitals we should review.

NHS Trusts and Boards

There were 217 NHS Trusts in England as of April 2021. We randomly sampled 67 to give 95% confidence, with

10% margin of error, in locating representative registers. (Initial randomisation included the Mid Staffs and Nightingale Trusts: the former had been included on the official NHS Trust list erroneously, as it was dissolved at the time of research: the latter was temporary, using seconded staff to deal with COVID-19 pandemic pressures. We therefore did not think it fair to judge by usual standards; these Trusts were removed and replaced.) In Scotland, there are 14 Health Boards. Because this is the first investigation of this type we are aware of, and the smaller number, we included all.

We searched organisations' websites for registers of

- 1. Board, governor, member or decision maker
- 2. Gifts and Hospitality.
- 3. Staff

If each of these registers were not immediately apparent, or combined, Trust sites were searched systematically (online supplemental appendix 1).

Sampling of NHS England Trust websites used a random number generator (via Google sheets), set against an alphabetical list of Trusts. In each case, the 'test' was of the recording process used to generate declarations, not the content of individuals' responses. We gathered specific data for each organisation (online supplemental appendix 2) using a search strategy online supplemental appendix 3) assessing whether the template adhered to all requirements set by NHSE (online supplemental appendix 4). These were assessed by two researchers independently and disagreements resolved by discussion.

Contacting Trusts: If neither researcher located each register, we emailed the media department of the Trust (online supplemental appendix 5requesting any publicly available register of interests. If there was no reply in 7 days we wrote again and recorded outcomes.

NHS Boards: Scotland

Preliminary searches found few public registers. Because we were not aware of any previous systematic analysis of registers held by NHS Scotland Boards, we used different methods in order to understand current practice.

In assessing current practice in Scotland we were interested in whether staff declarations were being requested



Table 4 Detailed analysis of NHS England registers
--

Entries	Who?	Value?	Purpose?	Date?	Mitigation?	Disclosure UK?
32	No: 2 Yes: 30 R: 2 (MDUK)	No: 15 N/A: 1 UK: 7 Yes: 9	No: 2 N/A: 8 P: 1 Yes: 21	UK: 2 Yes: 30	No: 18 P: 3 Yes: 11	No: 4 N/A: 25 P: 1 Yes: 2
Percentage	93	29	80.7	93	34	28

.MDUK, My Declarations United Kingdom; N, no; R, rolling (mydeclarationUK); UK, unknown; Y, yes.

and if so, published. We used the same searching methodology as used in English Trusts. In the absence of national guidance to publish declarations, we sent Freedom of Information (FOI) requests to each Board (online supplemental appendix 6) and requested published and unpublished registers, and recorded all. We assessed register categories against NHSE guidance in order to compare whether Scottish declarations captured more, less, or the same data as in England.

A 20% sample of these were checked with a second researcher.

CCGs: England

In 2020 there were 191 CCGs in England, merging into 135 CCGs in 2020-2021, many containing multiple entities with some shared and some separate registers. The random selection included geographical variety (Northumberland, North East London, Berkshire) as well as size (Milton Keynes CCG provides for a population of 260 000, Norfolk and Waveney 1.1 million). We altered our search strategy in accordance with NHS England guidance on register templates (online supplemental appendices 7, 8). More registers than anticipated were found (eg, seven registers in a single CCG). Because of resource limitations and an unknown denominator, we stopped searching after analysis of 68 registers in 15 CCGs repeatedly obtained similar results. All CCG entities had to contain relevant registers to meet the criteria.

Detailed analysis of a sample of NHS England registers

The random sample included a wide geographical spread, including Trusts which were mainly rural, mainly urban and tertiary (eg: Dorset, Birmingham, Middlesex, The Royal Marsden). NHS England guidance states declarations should 'contain enough information to be meaningful (eg, detailing the supplier of any gifts, hospitality, sponsorship, etc). That is, the information provided should enable a reasonable person with no prior knowledge should be able to read this and understand the nature of the interest. We discussed this with the patient group. We assessed financial declarations of decision makers using the framework of understanding 'who/what/where/when' of financial transactions, given the evidence of impact and ability to more consistently demarcate findings. Individual declarations were randomly selected from Trusts, themselves randomly selected. We intended to search a larger sample, but given the lack of clear denominator (staff members who made a financial DOI), variability in reporting systems and disclosures made and limited resources, we stopped assessing entries after all found regular deficiencies. If a declaration had no financial component, N+1 was used. Data were extracted from Trusts using 'mydeclarations' (a proprietary software brand used by many Trusts³²) to locate individuals. Registers with fewer than three entries were disregarded.

We assessed:

- 1. Type of financial interest.
- 2. Whether 'a reasonable person with no prior knowledge should be able to read this and understand the nature of the interest': who paid the money, what was the quantity, why and when was it paid, and what action was intended to mitigate it.

This was a search of staff Conflict of Interest (COI) registers. If the declaration was a 'gift' or 'hospitality', and the Trust had a gifts and hospitality register, this was searched to assess consistency.

Pharmaceutical company declarations were cross checked on Disclosure UK.

Private sector

With the patient group, we considered how to identify which organisations to examine. We assessed declarations on the five largest private hospital chains in the UK and the five top Google searches for 'private health clinics uk', including promoted sites, if not already captured. The Private Healthcare Market Investigation Order 2014³³ states that hospital operators must publish details of clinicians with shares or financial interests in the hospital or equipment. We assessed websites for statements relating to any disclosure of interests.

RESULTS

England: NHS Trusts

We found a total of 162 registers published by 67 Trusts (median: 2, range: 1-4, online supplemental appendix 9). Some registers were absent: We could not find all the relevant registers on 25 Trust websites; direct contact produced two further registers.

Of these, 21% of Board registers and 65% of governor registers were absent (table 1).



Box 1 Example of high-quality declarations

'Loyalty Interest - sits on one of the technology appraisal committees at NICE (decides on whether high cost drugs are cost effective for use within the NHS) (unremunerated).'

'Loyalty interest - excluded from the decision making process for the vacant post to avoid conflict of interest, and is two tiers of management above (family member) position.'

'Provision of advice to Janssen about the likely clinical benefits and/ or risks of one of their licensed products, Esketamine. The product is licensed for use in the UK, though neither Acute Mental Health Services nor the Trust currently prescribe it (July & Sep 2020). No financial interests in whether this medication is used or not.'

About 43% of Trusts published a decision maker register and 23% an 'all staff' register. About 46% of Trusts published a separate gifts and hospitality register, and of those that did not, 28% published it in a combined register elsewhere. Of 162 registers analysed (table 2), 29% were at least 14 months old, 24% contained all the categories recommended by NHS England and 35% were searchable either by alphabet or online search box. 69% of registers held by Trusts enabled a declaration of no interests to be made, and 26% asked for quantification of financial interests.

Scotland: Board Registers

All NHS Scotland Board members published registers of interest, however only one published a staff DOI register. Six of 14 Boards published a gifts and Hospitality (G+H) register (table 3).

Two registers obtained under FOI (online supplemental appendix 10) contained all NHS England template categories on gifts and hospitality. Of 33 registers available to inspect, 9 contained substantial retractions, for example, names of staff or types of interest for hospitality or sponsorship. Numerous examples of hospitality funded for by multiple pharmaceutical companies for 'Grand Rounds' or 'junior doctors meeting' had no further detail supplied. Other examples of difficult to interpret information were declarations such as 'honorarium', or 'consultancy' with no further detail supplied. Two health boards did not provide staff Registers of Interests under FOI, with one Board saying they were recorded at 'local level', not centrally recorded and spread across hundreds of departments; the other was described as not being in an easily

Box 2 Example of low-quality declarations

'I have been sponsored by pharmaceutical companies to attend Fertility meetings in the past.'

Declaring $\mathfrak E1$ worth of hospitality: 'I have no sight of the costs incurred by hospitality provider and am not prepared to speculate, and have therefore entered an arbitrary low sum. Hospitality was related to comfortable attendance at the meeting only.'

'Nine patents currently held, details available on request.'

'Speaking at various hospitals in China.'

'Grant sponsored by industry'

retrievable format. Two registers were empty but dated, hence the different denominators in some analysis. All had board member registers, and registers for gifts and hospitality, sometimes included in a Staff Register. One Board held a register purely for 'sponsorship'. Eight Boards had a register for all staff DOI, and one other for senior decision makers/managers only.

Detailed analysis of NHS England registers

On detailed examination (online supplemental appendix 11), we found instances of hospitality declared on a register of interest, but not on the gifts and hospitality register (table 4). Declarations made on a proprietary (mydeclarations.co.uk) included template questions including date, sponsor, description, value and recipient. However, this still allowed for error. For example, a nurse consultant declared income for paid talks as 'sponsorship' when this should have been categorised as outside (freelance) employment. We found instances where declarations had been made on DeclarationsUK, the industry open declarations initiative, but not on employers' websites. The proprietary website (mydeclarations) contained multiple categories, but not always a statement of actions taken in order to mitigate potential conflicts.32

Examples of high-quality and low-quality declarations from NHS Trusts are given in boxes 1 and 2.

Private sector

No public gifts and hospitality register was located on any assessed website (table 5).

Each published necessary Competition and Markets Authority statements relating to potential conflicts with the hospital (eg, shares and equipment ownership), but not conflicts of interest more broadly, either on each consultants' profile, or a central register. Each hospital chain/private clinic was contacted. Three replied confirming they published no other register. There was no reply after two contacts with the other hospitals. Of the five private health clinics listed first in a Google search for 'private health clinic', three provided a CMA statement; none provided gifts, hospitality or conflicts of interest registers (table 6, online supplemental appendix 12).

There were very high levels of gifts and hospitality register publication (table 7) and over two-thirds used NHS England standard template categories. Many governors declared their own GP practice as a potential COI.

DISCUSSION

Despite clear guidance in NHS England, Trusts are routinely failing to capture all of the information recommended in declarations, with only 24% publishing all categories of interest. While NHS Scotland Boards and CCGs routinely published Board registers of interest and gifts and hospitality registers, respectively, there were also large gaps. About 23% of CCG staff registers did not contain all recommended categories. Over a quarter

Gifts and hospitality	Declaration of interest	CMA compliance statement*
No	No	Yes
	No No No	No No No No No No No No

*Competition and Markets Authority Compliance Statements. CMA, Competition and Markets Authority.

(27%) of NHS Scotland Board registers contained redactions of some staff information on their declared conflicts and most (86%) staff registers were not publicly available. Over a third (35%) of registers from Trusts were designed to be searchable, mainly alphabetically. Some Trusts used specifically designed, searchable software allowing continuous rolling declarations. This had the potential to include all categories of professionals and types of register but was rarely used as such, with some categories unused, necessitating yet further registers, for example for board members. Additionally, wording on registers may cause confusion over whether a declaration was absent due to nothing to declare, or due to failure to comply with completion. Of registers published by Trusts, 69% made it possible for staff to make a positive declaration of no interests. Private clinics/hospitals had similar issues: the Competitions and Marketing Authority (CMA) statement was absent on two websites examined, but statements of interest included only those in relation to CMA stipulations and not more broadly, consequently potentially appearing complete when it is not. Even if organisations were complaint with publishing standard templates, meanings were often opaque.

For example, registers could state 'pharmaceutical shares' 'honorarium' or 'director of a management consultancy', but without information to interpret the nature and extent of conflicts. Lunches were frequently declared as paid by numerous companies for 'grand

	D
lable 6	Private sector public declarations

G+H/ DOI registers	СМА
No	Yes: by hospital
No	Yes: by consultant
No	No*
No	Yes: by hospital
No	No†
	No No No No No

^{*}Referrals needed for psychiatric appointments. †Referrals done internally from private GP to private

CMA, Competition and Markets Authority; DOI, declaration of interest; GH, gifts and hospitality.

rounds', without further detail. Only 10% of registers published by Trusts contained specific action to be taken regarding each type of declaration. Declarations were noted containing a self-justification, for example 'I have completed the gift register for all of the talks and other company links I have. These are all for individual episodes and I do NOT have any long term / contract based contracts with any pharma'. Based on discussions with our patient group, we provide examples of what we judged as high-quality statements (the who/what/when/why of the potential conflict), and low-quality statements (unlikely to have information to reasonably interpret the disclosure) (boxes 1 and 2).

Despite clear efforts to improve declarations, there was frequently ineffective DOI, not simply in terms of composition, but also in organisation and utility. Healthcare organisations commonly hold multiple registers of declarations, which can include board members, governors, decision-making staff, all staff, gifts and hospitality, sponsorship and for CMA stipulations. These may be combined or contained within separate documents. Some were absent, and while many organisations filed consistent, visible declarations, some were contained in minutes of meetings, individual biographies or only on direct request of Freedom of Information request.

There were also multiple instances of disclosure of non-recurrent small gifts from patients, for example, knitted items, hand made jewellery or flowers, with professionals justifying acceptance lest they be seen as rude. It seems inefficient and wasteful to scrutinise this when known concerns—particularly financial interactions with industry—are difficult to find and interpret, or not published. Further, governors of CCGs declaring where they are registered as patients is a potential breach of their privacy and security. While local sanctions are possible for failures to declare, numbers are not routinely

Strengths of our study include it being the first to examine in declarations practice post the 2016 English recommendations, and the first assessment of Scotland, and the private sector we are aware of. Limitations included challenges around fair sampling of CCGs, particularly as these were in flux over the period of our study. Mergers and boundary changes often made it unclear where registers should sit and over what timeframe. The planned investigation of primary care practices was withdrawn

BMJ Open: first published as 10.1136/bmjopen-2022-065365 on 4 November 2022. Downloaded from http://bmjopen.bmj.com/ on September 21, 2023 by guest. Protected by copyright

	Table 7	CCGs'	register	results
--	---------	-------	----------	---------

CCGs	Use of standard register	CCG with complete governor registers in all entities	Gifts and hospitality register	Register of interests	Other registers held
CCGs: 15 Entities: 28 Total registers: 68	No: 20 UK: 2 Yes: 46	No: 7 Yes: 8	No: 1 Yes: 27	No: 4 UK: 1 Yes: 10	Commercial sponsorship ¹
Percentage CCGs, Clinical Comr	68 missioning Groups; UK	53 , unknown.	96	67	

due to the pressures of caring for the population in the COVID-19 pandemic. In the absence of a clear denominator (number of private healthcare organisations in the UK) we made pragmatic choices about assessing the largest companies. This means we could potentially have missed areas of good practice.

While we are not aware of other similar work assessing registers of declarations NHS organisations in the UK, work has been done to assess the reliability of declarations made in a single location. For example, assessment of Declarations UK has found that around 40% of monies from the pharmaceutical industry to healthcare professionals was undeclared with large variations between companies making them.³⁴ This company-level perspective is important as it should allow for doublechecking that declarations are accurate, however, a voluntary system is not robust. This is also reflected across Europe, where, with few exceptions, the quality of data of payments to professionals is low. Similarly, authors of academic research in high-impact journals have been found to have frequently undisclosed financial interests.³⁵ Our research findings are in keeping with other types of registers or declarations, and questions whether systems of self-regulation are feasible.

To improve the situation, clarity is needed about the purpose(s) of declarations, and whether they are for simple transparency, or management. Asking individuals to self-judge the difference between a 'declaration' and a 'potential conflict' should be avoided. We are currently undertaking preliminary studies to find out the best way to obtain, display and manage declarations. We believe it is likely that studying potential improvements using studies within trials published in academic journals, hospitals and CCGs will be beneficial.³¹ Such studies will require quantitative and qualitative methods designed to understand concordance, utility and judgements and management of them by professionals and patients. Testing is important given the risk of unintended consequences, in particular 'moral license' which may result from declarations. Trials should match the purpose of declarations and may need to be adjusted and be capable of assessing harms. Technological assistance to do this could be utilised, but care should be taken not to increase workload in doing so.

Conclusion

Despite the creation of thousands of registers of interest in the UK, locating and interpreting them remains problematic with an organisationally chaotic system limiting their utility and efficiency. Most Trusts are not following NHS England guidance on publishing declarations. It may be better to concentrate greater efforts into making thorough, interpretable, declarations at high risk of producing conflicts, including sponsored educational events, while eliminating the need to stop 'overdeclaring' low value, non-recurrent gifts. It is important to consider what the purpose of declarations are: if others are expected to draw judgements on their potential impact, appropriate information has to be contained to achieve this. It is unknown whether registers are useful to the public or professionals. Although our analysis of the private sector had limitations, the absence of multiple registers makes it particularly prone to adverse influence. National guidance should be developed specifically for this sector. The lack of oversight and accountability of the current system is concerning.

Twitter Margaret McCartney @mgtmccartney

Acknowledgements The authors thank the advisory lay group: Lynne Craven, Brian Finney, Fiona Raje, Kath Samson.

Contributors The study was conceived by MM in partnership with the lay group, methodology organised by MM. HF. FS and CH. Data collection and assessment were done by CM, RBH, MM and RM. Organisational elements were provided by CM, MM and RM. Data analysis was done by MM, CM, RM, FS and CH. Drafting and editing by MM, FS and CH. Revisions after peer review were done by MM and FS. MM is acting as guarantor.

Funding MM is funded by the Chief Scientist Office Scotland, RBH and RMcD had summer medical studentships from the University of St Andrews. No specific funding for this project was otherwise received. Grant award number: N/A

Competing interests MM and CH have written, broadcast and campaigned around issues pertaining to conflicts of interest which has included paid work.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.



Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs

Margaret McCartney http://orcid.org/0000-0002-7238-6358 Frank Sullivan http://orcid.org/0000-0002-6623-4964

REFERENCES

- 1 ABPI. APBI code of practice for the pharmaceutical industry. ABPI, 2021.
- 2 Hansen C, Lundh A, Rasmussen K, et al. Financial conflicts of interest in systematic reviews: associations with results, conclusions, and methodological quality. Cochrane Database Syst Rev 2019:8:MR000047.
- 3 Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003:289:454–65.
- 4 Spithoff S, Leece P, Sullivan F, et al. Drivers of the opioid crisis: an appraisal of financial conflicts of interest in clinical practice guideline panels at the peak of opioid prescribing. PLoS One 2020;15:e0227045.
- 5 Spurling GK, Mansfield PR, Montgomery BD, et al. Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. PLoS Med 2010;7:e1000352.
- 6 Krimsky S, Rothenberg LS. Financial interest and its disclosure in scientific publications. JAMA 1998;280:225–6.
- 7 Hearing before the human resources and Intergovernmental relations Subcommittee of the Committee on government operations house of representatives one hundred first conference first session. 13/6/89 us government printing office. Available: https://books.google.co.uk/books?id=z2HEes4elKEC&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false
- 8 International Committee of Medical Journal Editors. Conflict of interest [Conflits d'intérêts]. CMAJ 1993;148:2141–2.
- 9 Uniform requirements for manuscripts submitted to biomedical iournals. JAMA 1997:277:927–34.
- 10 Macdonald H, McCartney M, Heneghan C, et al. Doctors' conflicts of interest. BMJ 2020;370:m3247.
- 11 Disclousure UK. Available: https://www.abpi.org.uk/reputation/ disclosure-uk/
- Moran V, Allen P, McDermott I, et al. How are clinical commissioning groups managing conflicts of interest under primary care cocommissioning in England? A qualitative analysis. BMJ Open 2017;7:e018422.
- 13 Government response to the report of the independent medicines and medical devices safety review. Available: https://assets.

- publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf [Accessed 26 Jul 2021].
- 14 Feldman HR, DeVito NJ, Mendel J, et al. A cross-sectional study of all clinicians' conflict of interest disclosures to NHS Hospital employers in England 2015-2016. BMJ Open 2018;8:e019952.
- 15 Ross JS. Kept in the dark: Scotland rejects "sunshine" legislation. BMJ 2019;364:l1379.
- 16 Managing Conflicts of Interest in the NHS. Guidance for staff and organisations. NHS England, 2017.
- 17 NHS (Scotland) circular no 1989 (10) (Gen) 32. Available: https://www.sehd.scot.nhs.uk/mels/GEN1989 32.pdf
- 18 Corporate Governancegovernance in the NHS: supplementary guidance. The Scottish office. Available: https://www.sehd.scot.nhs. uk/mels/1994 80.pdf [Accessed 2 Aug 1984].
- 19 Smith R. Conflict of interest in clinical research: opprobium or obsession? The Lancet 1997;349:1703.
- 20 Open payments data. Available: openpaymentsdata.cms.gov
- 21 Propublica, dollars for docs. Available: https://projects.propublica.org/docdollars/
- 22 Lexchin J, Fugh-Berman A. A ray of sunshine: transparency in physician-industry relationships is not enough. *J Gen Intern Med* 2021;36:3194–8.
- 23 Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. Am J Med 2001;110:551–7.
- 24 General Medical Council (UK). Financial and commercial arrangements and conflicts of interest. Available: https://www.gmcuk.org/ethical-guidance/ethical-guidance-for-doctors/financial-andcommercial-arrangements-and-conflicts-of-interest/financial-andcommercial-arrangements-and-conflicts-of-interest
- 25 Silverstein RL. In the interest of transparency. The Hematologist 2019;16.
- 26 Does conflict of interest disclosure worsen bias? PLOS Medicine.
- 27 Rose SL, Sah S, Dweik R. Patient responses to physician disclosures of industry conflicts of interest: A randomized field experiment. In: Organizational behavior and human decision processes, 2019. ISBN: ISSN 0749-5978.
- 28 Horton R. Conflicts of interest in clinical research: opprobrium or obsession? *The Lancet* 1997;349:1112–3.
- 29 First Do No Harm the report of the Independent Medicines and Medical Devices Safety Review, 2020. Available: https://www. immdsreview.org.uk/downloads/IMMDSReview_Web.pdf
- 30 House of commons health CommitteeThe influence of the pharmaceutical industry. fourth report of session 2004–2005, 2005. Available: http://www.publications.parliament.uk/pa/cm200405/ cmselect/cmhealth/42/42.pdfDate
- 31 Is the current system for health professionals declaring potential conflicts of interest fit for purpose? public registration. Open Science Network https://osf.io/e7gtq
- 32 Declare C. Available: https://www.civica.com/en-gb/product-pages/ declare/
- 33 . Competition and markets authority order, 2014. Available: https://assets.publishing.service.gov.uk/media/59031bc240f0b606 e3000265/private-healthcare-market-investigation-order-2014-as-amended.pdf
- 34 Mulinari S, Ozieranski P. Disclosure of payments by pharmaceutical companies to healthcare professionals in the UK: analysis of the association of the British pharmaceutical industry's disclosure UK database, 2015 and 2016 cohorts. BMJ Open 2018;8:e023094.
- 35 Baraldi JH, Picozzo SA, Arnold JC, *et al.* A cross-sectional examination of conflict-of-interest disclosures of physician-authors publishing in high-impact US medical journals. *BMJ Open* 2022;12:e057598.