Vaccine 38 (2020) 4183–4190

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Is flu vaccination opt-out feasible? Evidence from vaccination programme implementers and managers in the English National Health Service

Sadie Bell [a,*], Tracey Chantler [a], Pauline Paterson [b], Sandra Mounier-Jack [a]

[a] Department of Global Health and Development, Faculty of Public Health and Policy, London School of Hygiene & Tropical Medicine, London WC1H 9SH, United Kingdom
[b] Department of Infectious Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London WC1E 7HT, United Kingdom

ARTICLE INFO

Article history:
Received 16 February 2020
Received in revised form 3 April 2020
Accepted 10 April 2020
Available online 04 May 2020

Keywords:
National Health Service (NHS)
Healthcare worker flu vaccination
Declination
Opt-out

ABSTRACT

Background: In 2018/19, English NHS trusts (NHSTs) implemented an 'opt-out' policy for seasonal flu vaccination in frontline healthcare workers (HCWs). HCWs declining the vaccination were asked to sign an opt-out form and provide a reason for their decision. In addition, HCWs working in higher risk hospital environments (e.g. oncology) were asked to inform their manager about their declination decision. The policy aimed to provide greater insight into reasons for vaccination decline and information from HCWs in higher risk areas was intended for use in considering HCW redeployment. This study investigated the feasibility, acceptability, and perceived value of the policy during the 2018/19 flu vaccination season.

Methods: We conducted semi-structured interviews across 9 NHSTs in England with different levels of HCW flu vaccination uptake in 2017/18. We interviewed 30 vaccination programme implementers and 27 managers.

Findings: The purpose of the policy was poorly understood, and interviewees did not know how data on decliners was being used. Most NHSTs tried to collect the personal details of decliners and, in some instances, these were recorded in Electronic Staff Records and reported to line-managers for action. This created strain on employer-employee relationships, leading to decliners refusing to complete opt-out forms and some vaccinators not implementing the policy. None of the NHSTs had a redeployment policy for decliners, arguing that this was impractical due to strain on staffing levels.

Conclusion: A flu-vaccination opt-out approach for HCWs did not appear acceptable in our sampled NHSTs, due to a lack of clear messaging about its purpose and complicated implementation. To promote an opt-out approach effectively, there needs to be clear communication of its purpose, which should be to explore reasons for decline rather than identify and 'push' decliners to vaccinate, so as not to damage staff relationships. NHSTs should involve their workforce in developing flu vaccination approaches.

© 2020 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

1. Background

Vaccinating healthcare workers (HCWs) against influenza (flu) is recommended to protect HCWs, their patients and families from flu [1-3]. NHS England's[1] ambition is for every frontline National Health Service (NHS) HCW (i.e. those who interact directly with patients) to receive an annual flu vaccine. NHS employers are responsible for arranging flu vaccination for their employees.

In England, although substantial improvements in HCW flu vaccination uptake have been made [4] and vaccination rates are higher relative to other European countries [3,5], the 2018/19 rate of 70.3% fell short of the 100% NHS England ambition [6]. In addition, uptake rates in England vary widely between NHS trusts (NHSTs), from 36.8% to 95.4% in 2018/19, with a median uptake of 75.4% [6].

In 2018/19, to promote HCW flu vaccination uptake all NHSTs in England were asked by NHS England and NHS Improvement[2] to implement an 'opt-out' flu vaccination policy for frontline NHS workers which involved a declination form. The decision was made following an NHS England and NHS Improvement consultation and evidence review with national clinical leaders and trade unions [7]. As part of this policy, vaccinators were required to:

* Corresponding author.
E-mail address: Sadie.bell@lshtm.ac.uk (S. Bell).

[1] NHS England is an executive non-departmental public body that provides strategic direction for the National Health Service (NHS) in England.

[2] NHS Improvement support foundation trusts and NHS trusts to promote consistently safe, high quality and compassionate care for patients.

https://doi.org/10.1016/j.vaccine.2020.04.026
0264-410X/© 2020 The Authors. Published by Elsevier Ltd.
This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

1) ask staff declining flu vaccination to tick anonymously that they had read the following declination statement and provide a reason for non-immunisation: *'I know that I could get flu and have only mild symptoms or none at all; and that because of this I could give flu to a patient. I know that vaccination is likely to reduce the chances of me getting flu and of me passing it to my patients. But I still don't want the vaccine*'. A template form was provided and could be adapted by NHSTs (Fig. 1).
2) ask staff working in 'higher-risk' clinical environments (such as haematology, oncology, bone marrow transplant, neonatal intensive care and special care baby units) to confirm to their clinical director/ head of nursing/ head of therapy whether or not they had been vaccinated.

The policy did not mandate completion of the declination form or the self-reporting of vaccination decline by staff in 'higher-risk' environments.

The policy required NHSTs to report the number of vaccination decliners via 'ImmForm' (a platform used to order vaccinations and to record uptake data) for Public Health England reporting purposes. NHSTs were told that this information would 'contribute to the development of future vaccination programmes'. Information on staff working in 'higher-risk' environments was to be held locally so that NHSTs could take appropriate steps to maintain the overall safety of the service, including considering changing the deployment of staff within clinical environments if that was compatible with maintaining the safe operation of the service [7].

Form to be potentially co-branded by NHS organisation and key trade unions

Dear colleague,
Did you know that 7 out of 10 front line NHS staff had the flu vaccine last year, and in some departments more than 9 out of 10 staff were vaccinated?

The flu jab gives our body the information it needs to fight the flu, which stops us from contracting and spreading the virus. For those of us who work in care settings, getting the flu jab is an essential part of our work. In vaccinating ourselves we are protecting the people we care for and helping to ensure that we are able to provide the safest environment and effective care for patients.

We want everyone to have the jab. The sooner you get it, the more people you can protect. We hope that you will agree to having the vaccine – this really helps to protect patients, you and your family. But, if you choose not to have the flu vaccine, we want to understand your reasons for that by filling in this anonymous form.

Signed

Chief Executive, Medical Director, Director of Nursing, and Trade Union representative

Please tick to confirm that you have chosen not to have the vaccine this year:

- ○ I know that I could get flu and have only mild symptoms or none at all; and that because of this I could give flu to a patient. I know that vaccination is likely to reduce the chances of me getting flu and of me passing it to my patients. But I still don't want the vaccine.

Please tick each of the boxes below that apply to your decision not to have the jab.

I DON'T WANT TO BE FLU VACCINATED BECAUSE:

- ○ I don't like needles
- ○ I don't think I'll get flu
- ○ I don't believe the evidence that being vaccinated is beneficial
- ○ I'm concerned about possible side effects
- ○ I don't know how or where to get vaccinated
- ○ It was too inconvenient to get to a place where I could get the vaccination
- ○ The times when the vaccination is available are not convenient
- ○ Other reason – please tell us here
  >_____

Thank you for completing this form

Fig. 1. Opt-out template sent to NHSTs.

Declination forms are considered unlikely to increase flu vaccination rates in HCWs strongly opposed to vaccination but may prompt undecided staff to vaccinate [8]. HCWs may also be more likely to vaccinate if they find it more inconvenient to complete a declination form than to vaccinate [8].

Evidence on the effectiveness of declination policies is reported to be of very-low to low quality but indicates their potential to improve vaccination uptake [9-12]. A recent systematic review reported that declination policies, delivered as a "soft mandate" (e.g. without enforcement or without severe consequences), had the largest independent effect on increasing flu vaccination uptake short of mandating vaccination [13].

Determining the effectiveness of declination polices is difficult given that they are often delivered concurrently with other interventions (e.g. incentives, changes in communication) [10,14]. The comparability of declination policies is also problematic due to variability in how declination forms are worded (e.g. language and content) and delivered (e.g. paper-based, online, completed with a vaccinator); whether completion of declination forms is mandatory; and whether non-completion carries any penalties [15].

Declination policies have mixed acceptability amongst HCWs, with some considering the approach appropriate and others viewing it as coercive [8,16]. Scepticism has been reported amongst HCWs about the purpose of declination forms, with concerns that information provided may be used against them e.g. if a patient in their care contracts flu [8].

This study investigated the implementation of an 'opt-out' policy that used a declination form in NHSTs during the 2018/19 flu vaccination season. We explored how the policy was applied in different NHSTs, and staff perceptions and experiences of delivering the HCW flu vaccination programme with regards to the feasibility, acceptability and perceived value.

2. Methods

Cross-sectional semi-structured interviews were conducted with NHS staff involved in delivering vaccinations and managing the HCW flu vaccination programme for 2018/19 in acute NHSTs.

2.1. Study sites and recruitment

We used a maximum variation sampling approach to attain a diverse sample of NHST recruitment sites based on three characteristics: 1) HCW flu vaccination coverage at the NHST for 2017/18, 2) the number of frontline HCWs in the NHST in 2017/18, and 3) the geographical location of the NHST (see Table 1).

NHS Improvement were involved in recruiting the sites for this study through their communication links with NHST Medical Directors and Chief Nurses. Twenty NHSTs from a wide range of geographical areas in England, with different workforce sizes, were initially approached through email communication from NHS Improvement. Ten of these NHSTs achieved an HCW flu vaccination uptake equal to or greater than 75% in 2017/18 and the other 10 had uptake rates lower than 75%.

Nine of the 20 contacted NHSTs became study sites.

2.2. Interviews

Interviewees were purposively sampled to represent vaccination programme implementers and managers from different professional groups (e.g. infection control nurses, staff nurses, ward and department managers) and a range of hospital settings (e.g. theatres, oncology units).

The nine NHSTs that agreed to take part in the study provided a list of flu vaccination programme implementers and managers to contact. Members of the research team (SB, TC, PP and SMJ) emailed 8–10 nominated managers and vaccinators from each NHST with a short study summary and invited them to respond if interested in participating.

Participants were offered the choice of being interviewed face-to-face in their workplace or over the phone. Written informed consent was obtained from each participant. The interviews lasted approximately 30 min and were semi-structured. Topic guides were used to assist the interviews. These included questions about the implementation of the HCW flu vaccination programme and the opt-out system, focusing on the acceptability of the opt-out approach to managers, implementers and HCWs approached for vaccination.

All interviews were audio-recorded with permission and reflective notes were taken during the interviews. Interviews were conducted by SB, TC, PP and SMJ. To ensure the accuracy and credibility of interviewer interpretations, interviewers summarised and probed participant responses during interviews.

2.3. Data analysis

Interviews were transcribed verbatim and analysed thematically by SB, TC, PP and SMJ using the stages outlined by Braun & Clarke [17]: data familiarisation, coding, theme identification and refinement. Interviews were coded using codes generated from the interview topic guide. Following the coding of each interview, codes were collated to generate broader themes.

To avoid interpretation biases and promote the credibility of our analysis, we reviewed the interviews independently and came together to discuss our analysis and agree upon codes and themes.

Table 1
Participating NHS trusts and interviewees.

NHST details and recruitment					
NHST	No. of HCWs involved with direct patient care 2017/18	Flu vaccination uptake in all frontline HCWs -September 2017 to February 2018 (%)	Managers (n 27)	Vaccinators (n 30)	Total no. of participants
1	~7000	>90%	2	4	6
2	~3000	>80%	5	3	8
3	~6000	>80%	3	3	6
4	~4000	>80%	2	2	4
5	~1500	70–80%	1	1	2
6	~10000	70–80%	4	5	9
7	~6000	50–60%	5	3	8
8	~3500	50–60%	3	3	6
9	~3000	50–60%	2	6	8
					Total: 57

Data collection and analysis were undertaken concurrently. We used NVivo 11.0 to manage the data and aid the analysis.

2.4. Ethical approval

The study received full ethics approval from Public Health England's Research Support and Governance Office (RSGO).

3. Findings

3.1. Participants

Table 1 provides an overview of the 9 NHSTs that we recruited from and the number of vaccinators and managers recruited from each trust. HCW flu vaccination uptake in the NHSTs ranged from just over 50% to over 90%. Four NHSTs were categorised as achieving higher uptake in 2017/18 (in excess of 80%), two as having medium-high uptake (between 70 and 80%), and three as having lower uptake (less than 60%).

We interviewed 57 participants in total, 27 of whom were categorised as managers and 30 as vaccinators. Programme managers included matrons, lead nurses and department managers. Vaccinators included representatives from infection control and occupational health teams, and peer-vaccinators from a range of hospital departments (e.g. midwifery, theatres).

We identified seven main themes from the interviews; 1) variable policy implementation; 2) concerns about over-emphasising the policy; 3) record keeping and compromised staff confidentiality; 4) feelings of victimisation amongst staff; 5) limited policy value and perceived negative consequences; 6) impracticality of deploying or re-deploying unvaccinated staff; and 7) attitudes towards mandating vaccination.

3.2. Variable policy implementation

NHST trusts had adopted different approaches to implementing the opt-out policy. One of the NHSTs, which was classed as having higher uptake, had adopted a mandatory opt-out flu vaccination policy for staff already in post (requiring staff to sign that they are declining the vaccination but not making it compulsory to provide a reason) and a contractually mandatory approach for new starters (with exceptions made for valid medical, religious and conscientious objections). The rest of the NHSTs had implemented a non-mandatory 'opt-out' approach for all staff – asking but not requiring staff to sign declination forms and provide reasons for refusal. None of the NHSTs reported asking decliners from higher-risk environments to report their vaccination decision to their line managers.

NHSTs used electronic forms (2), paper forms (5), or a combination of paper and electronic forms (2) to record consents and declines. The opt-out template (Fig. 1) was largely adapted as it was reported to be unclear and too lengthy. Staff from two NHSTs stated that their form was difficult for some staff to understand and complete due to language and literacy barriers.

NHST adaptations to the template included removing the tick-box options for decline in favour of open-text responses. Others only recorded the decision to decline and did not provide a designated space to document a reason. At all but one of the NHSTs the forms had been implemented with a section for staff to record their name, job role, and to provide a signature. This deviated from the NHS template, which only asks for anonymous responses.

Only one NHST did not ask for or link decliner responses with staff personal details. This trust used an electronic form that was sent to all staff members via email, separate from communication about vaccination sessions. It was the only NHST that provided an opt-out form to every member of staff. The timing chosen by this NHST for circulating this electronic form (a couple of months into the programme) was carefully planned to occur after the peak time for vaccinations to avoid the risk of encouraging more declines.

All other NHSTs provided the form on an opportunistic basis during vaccination clinics or roving vaccine sessions. One NHST had combined the flu vaccination opt-out form with a hand and skin assessment. As the skin assessment was a mandatory requirement at this NHST, the need to complete this placed greater emphasis on also completing the flu vaccination opt-out section of the form.

3.3. Concerns about over-emphasising the policy

NHSTs acknowledged the need to make staff aware of the opt-out policy and its purpose. However, NHSTs were careful not to place too much emphasis on policy communication due to concerns about normalising decline instead of vaccine acceptance. NHSTs wanted to focus their messages on promoting vaccination.

> *'We tried not to communicate it to staff straight away. So, we didn't say, you can have it, or you can't have it and you sign the disclaimer. We pushed for people to have the vaccine.' (NHST-9, lower uptake)*

In some instances, communication of the policy appeared to be so downplayed that several vaccinators and managers were not aware of the policy themselves. Limited communication to vaccinators also led to incorrect beliefs that recorded declines would be removed from the denominator in reporting uptake.

> '*We thought we might get those numbers taken off our denominator. I think we were a bit misinformed because when we came to input, we just had, the number of the refusals didn't get taken off our denominator on the input.*' *(NHST-4, higher uptake)*

3.4. Record keeping and compromised staff confidentiality

Vaccinators were not routinely given a list of all eligible staff at a ward or departmental level to mark off once approached for vaccination. In some cases, peer-vaccinators chose to develop informal records of approached staff – whilst also formally documenting consents and declines as per NHST policy. Vaccinators considered the only way to gain an accurate record of vaccination declines would be to obtain a complete list of staff by area, and to ensure that all staff on a ward were accounted for (e.g. those that have been vaccinated, declined, or are on maternity leave or long term sick leave). As well as enabling vaccinators to monitor uptake, keeping these informal records also helped vaccinators to avoid re-approaching staff that had declined the vaccine.

Although considered beneficial to gain accurate uptake data, the use of staff lists could present problems – in terms of maintaining staff confidentiality and avoiding the direct targeting of staff to vaccinate. In one instance, a vaccinator noted the vaccination status of staff on work rota allocation sheets, creating a sense of pressure for staff to be vaccinated or document their decline.

> *'on our allocation sheets, we have the listings of who's working that day, and I'll put in pencil next to them, needs the vaccine. . ..which can either prompt the people to remind them to have it, or it can be quite threatening if they really don't want to have it. I do it for everybody, yes. It's just a blanket thing, and they come to me and tell me they don't want me to . . . There's two people who tell me, stop putting that thing next to my name, and I'll go, why? You've not had your vaccine. Why? So, until they do the decline form, I'll just keep putting it against their name.' (NHST-3, higher uptake)*

In several instances, staff that had declined vaccination, or those that had not yet made the decision to vaccinate or decline, were reported by vaccinators to their line managers who would then discuss their decision with them. This could make decliners feel forced to vaccinate.

At several NHSTs, staff were concerned about vaccine uptake data being recorded on Electronic Staff Records (ESRs), and the potential repercussions of documenting vaccine decline in this way.

'What worried people last year was that we entered it onto our Electronic Staff Records (ESR), and people were really anxious about the fact, you know, I've refused a vaccination and you're putting it on ESR. So, there was a bit of, there was a bit of controversy regarding that.' (NHST-4, higher uptake).

Staff were concerned that declines may be used against them, and if included on their ESR potentially affect their employment. At other NHSTs, data were recorded on systems separate to ESR, including occupational health software. Occupational health software is linked to staff occupational health records which are not shared with the employer.

3.5. Feelings of victimisation amongst decliners

Vaccinators and programme managers across all NHSTs reported that responses to the opt-out programme amongst staff approached for vaccination were mainly negative. Vaccinators and programme managers found that decliners felt victimised and expressed concerns about identifiable data being recorded as per the implementation of the policy by some NHSTs. As the flu vaccine is not mandatory, vaccinators found that staff members felt it was unreasonable to be asked to provide their reasons for decline and were worried their decision may be held against them.

'I think because there's enough pressure within the Trust to have the flu vaccine… it kind of feels like Big Brother is watching you and we're going to single you out, and I don't think that's a good approach' (NHST-7, lower uptake)

Two NHSTs also reported that medical unions were concerned about the opt-out policy and advised staff not to have their declines recorded.

'The professional bodies and trade union representatives are quite hot. When a staff member says I don't want to have it, and if they're in earshot of the infection control nurse trying to explain the reasons why to have it, I get feedback that, "They said they don't want it, you should leave it at that. Don't tell them lies. They don't want it; they don't want it. End of story." They don't want a national directive coming out…. the unions are really against that.' (NHST-2, higher uptake)

According to vaccinators some decliners could be aggressive and hostile when they were asked to complete an opt-out form and asked to provide their identifiable details. To cater for decliners' reluctance to provide their name and reasons for non-immunisation some vaccinators adapted their delivery of the opt-out policy.

'This year what I've said is, just get them to write why they don't want it, so if they've written, "None of your business" I've actually got, I'm able to provide the Board with a list of reasons that people have given me for not having the flu vaccine. But what I've said is, if they don't want to answer then you [the vaccinator] just write, "Health Care Assistant or Doctor won't answer"' (NHST-2, higher uptake)

At one NHST, a vaccinator reported that a member of staff had raised a formal complaint about feeling 'bullied' into having the vaccine. Vaccinators often felt uncomfortable in implementing the opt-out policy due to resistance and hostility from staff. At three NHSTs, some vaccinators had stopped asking staff to record their names in favour of just recording reasons for decline or had even stopped using opt-out forms.

3.6. Limited policy value and perceived negative consequences

Only one NHST reported a potential benefit of the policy, and this was amongst a minority of vaccinators. These vaccinators felt that it helped to reflect their efforts in approaching staff, even if they went on to decline the vaccine.

'I do think it's a good idea, because it just means that you have got some evidence that you have approached people. That for the Department of Health is good because it means you've looked at and at least asked so many people' (NHST-9, lower uptake)

Vaccinators reported that implementing the policy generated higher workloads and thought it could prove to be detrimental as it had the potential to normalise the option to decline immunisation. Vaccinators and managers from higher performing NHSTs were particularly concerned that the policy could have a negative effect and thought that collecting reasons for refusal would not be that insightful. In higher performing NHSTs it was thought that concentrating on the opt-out policy would be a waste of resources.

'When you're vaccinating nearly … well, let's say 93% of the organisation, am I going to spend all the time concentrating on the 7%? It's a waste of our time.' (NHST-1, higher uptake)

Some vaccinators and managers were also sceptical about the ability to implement the opt-out policy. All NHSTs reported that obtaining completed opt-out forms was a struggle and that decliners were particularly reluctant to link their names with reasons for refusal. It was also reported that decliners would try to avoid contact with vaccinators.

There were also concerns that the focus on opt-out form completion resulted in missed opportunities for meaningful conversations about individual's hesitancy to be vaccinated against flu.

'[The form] it's too long and lengthy. They [staff] don't have time to read all this, and they'd rather not fill the form in. It does make a lot of sense, but it's too lengthy, and it's better if it's in a conversation as opposed to that [the form].' (NHST-3, higher uptake)

Several NHSTs commented that the reasons for decline were broadly known and could not understand the purpose of the opt-out policy. Vaccinators and managers considered that the only way to gain a better understanding of the reasons for decline would be through deeper discussion with decliners.

3.7. Impracticality of deploying or re-deploying unvaccinated staff

None of the NHSTs had a policy for deploying or re-deploying HCWs declining the flu vaccine from working in hospital areas with particularly high-risk patients such as those with specific immune suppressed conditions where the risk of contracting flu may be most harmful. It was considered impractical to deploy staff on this basis, given staffing levels, and untenable as the vaccine is not mandatory.

One NHS trust, however, acknowledged that this approach had been discussed at flu meetings.

'Our infectious diseases control unit wanted to do that, you know, if you haven't had your flu vaccine, you can't work on the wards, but it didn't happen in real life, it would be impossible to pilot. And people also would, I think, walk out' (NHST-4, higher uptake)

Since influenza vaccination does not provide full protection against illness, NHSTs stressed that staff should be taking universal and transmission-based precautions (e.g. hand hygiene compliance, wearing personal protective equipment) when caring for patients with or suspected of having influenza. In addition, most NHSTs considered all areas as high-risk, which would be a challenge for deploying unvaccinated staff.

3.8. Attitudes towards mandating vaccination

With the exception of interviewees from one NHST that had implemented mandatory vaccination, and two NHSTs that were struggling with lower uptake, it was generally thought that HCW flu vaccination should not be made mandatory. Lower performing NHSTs felt that resorting to mandatory vaccination may be their only way of improving uptake.

'Personally, I am a fan, but I think it will cause some issues. But then, if it comes out nationally, then it helps us a great deal because then we say, "Well we've got no choice." So a national programme on mandatory flu vaccination would be helpful.' (NHST-6, lower uptake)

The majority of interviewees considered mandatory vaccination to be logistically problematic and potentially impossible to implement. It was felt that staff should be able to exercise choice around the decision to vaccinate and it was a staff right to be able to decline. The NHST that had implemented contractual mandatory vaccination for new starters had experienced a negative reaction from staff.

'[It] did create a lot of angst, and I did get a lot of people trying to wriggle out of it or trying not to have it, and there was lots of people giving me lots of reasons why they couldn't or shouldn't have it.' (NHST-5, medium-high uptake)

It was also difficult for this NHST to enforce mandatory vaccination, and they had experienced legal challenges and clashes with trade unions in implementing the policy.

It was felt that normalising flu vaccination by making it '*part of a trust's culture*' was the only feasible way of improving HCW flu vaccination uptake.

4. Discussion

A key rationale for introducing the opt-out policy was to provide insight into reasons for non-immunisation to inform and help design strategies for improving the uptake of HCW flu vaccine vaccination [9,10,18]. The policy also asked staff working in 'higher-risk' clinical environments to inform their clinical director/ head of nursing/ head of therapy of their vaccination decision.

In our study, we found that the purpose of the opt-out policy was not well understood by vaccinators, managers or vaccination decliners and interviewees. A lack of clarity around the reason for introducing opt-out led to vaccinators and managers implementing the policy in different ways, and fuelled HCW concerns about the policy motives. None of the NHSTs discussed encouraging staff to share their vaccination declination decisions with their managers.

Although the opt-out template sent to NHSTs advised for the collection of anonymised responses from staff, most NHSTs were, at least initially, also requesting personal details (e.g. name, job title, department). Personal data collection appeared to have been undertaken due to a lack of understanding around the purpose of the policy, and as a way of evidencing vaccinator efforts. In collecting personal data, HCWs felt that the policy could be used to 'name and shame' decliners, and many were concerned about who might be accessing the data and potential employment implications, particularly if the information was recorded in their professional records. Concerns around the linkage of declination decisions with personal details were also expressed by professional bodies and unions. Other studies have also reported healthcare worker concerns around the stigmatisation of decliners and potential negative consequences of signing declination forms [8].

As NHSTs found that decliners were largely reluctant to complete the forms and provide their reasons, the policy was not particularly effective in shedding new light on reasons for decline. In addition, the adaptation of opt-out forms by some NHSTs, so that it included no information on reasons for decline, meant that it could not be used as a tool to look at why HCWs were declining the vaccine. When this happened, this shifted the purpose of the policy to be a means of collecting personal details on decliners (either formally or through informal lists), that were sometimes fed back to line-managers for them to re-approach declining staff and 'push' vaccination. The use of the opt-out forms was often reported to detract away from, rather than facilitate, a meaningful discussion with decliners around reasons for refusal. This fuelled a negative employer-employee relationship, which may have hardened the stance of decliners.

Vaccinators and managers were also particularly concerned that the use of opt-out could increase vaccination declines in higher performing trusts, raising the question of whether the policy is suitable for trust-wide use.

Evidence supporting the use of opt-out policies is lacking in quality and has come from studies conducted outside of the UK [9], in the US and Japan, and the context of these studies and their applicability to the NHS needs greater consideration. In one example, declination forms were used in combination with making vaccination mandatory to work in 'high-risk' areas [19]. However, this approach relies on having a moveable and large enough workforce. In our study, we found that none of the trusts had the capacity to redeploy HCWs out of 'higher-risk' areas.

Currently, there are strict guidelines about NHS frontline worker vaccination against other infectious diseases e.g. hepatitis B, tuberculosis [20]; however, mandatory flu vaccination remains under debate [7,21]. The mandating of HCW flu vaccination is a divisive subject, with arguments against mandating focused on protecting individual autonomy and those for emphasising benefits to the workforce and patients [22,23]. Most interviewees in this study did not support the implementation of mandatory flu vaccination in HCWs, and the NHST that had implemented a mandatory approach was experiencing major challenges to its implementation.

Many NHSTs that have seen substantial improvements in vaccination uptake have achieved this through using innovative approaches to improve vaccine accessibility and acceptability, rather than through mandating. Instead of mandating vaccinations, vaccination can be more effectively promoted through changing the 'choice architecture' – that is, altering the environment in which people make their vaccination decisions and steering them towards vaccine acceptance [24]. Psychology and behavioural economics provide some possible approaches [25]. For example, the framing of vaccine messages is important and highlighting the costs of not being vaccinated (loss frame) rather than the benefits of getting vaccinated (gain frame) may work more effectively to promote vaccination [25-27]. Another approach that may encourage uptake is to make vaccination messages personal or relatable [25], and tailored to trusts by including trust HCWs in their messages. It has also been found that messages highlighting the soci-

etal rather than individual effects of vaccination also work well to promote vaccination [28].

Asking staff to sign up to a time slot for vaccination may also encourage uptake, as it has been found that people are more likely to put off tasks that do not have a time commitment (time-inconsistent behaviour) [25]. One of the highest performing NHSTs in this study announced vaccination sessions on a weekly basis, rather than releasing vaccination dates all at once, which they felt encouraged staff to vaccinate promptly and avoid missing the vaccination [29].

A commonality between successful approaches is that they encourage but do not pressurise staff to vaccinate. Respecting different views on vaccination rather than naming and shaming decliners is crucial [30]. Approaches to improve healthcare worker flu vaccination should be tailored to NHS trusts, exploring the specific barriers that are affecting uptake at an individual and staff-group level [31]. The opt-out approach, if used in an anonymised format, could make a good contribution to understanding these factors – where trusts are struggling with uptake and do not understand the reasons why. Importantly, there needs to be greater evidence on the effectiveness of using an opt-out policy in the NHS context, with the piloting of the approach in NHS trusts prior to national roll-out. In line with NICE guidelines [9], we recommend that trusts seek the input and involvement of their workforce in developing their flu vaccination approaches, including the use of opt-out.

4.1. Study strengths and limitations

A major strength of this study was our ability to recruit vaccinators and managers from a wide range of NHSTs, across several geographical locations and with different levels of HCW flu vaccination uptake and workforce sizes. However, there were some limitations.

By recruiting vaccinators and managers that were initially approached by NHST Medical Directors and Chief Nurses, this may have also introduced a bias in who took part in the research. We may have been more likely to have interviewed vaccinators and managers that felt obliged to discuss their experiences in a positive light.

Interviews were limited to vaccinators and managers and further research with HCWs would be beneficial to gain staff perspectives on being approached for vaccination and the opt-out policy.

5. Conclusion

For the 2018/19 healthcare worker flu vaccination season, NHSTs were requested to implement an 'opt-out' policy. This involved asking staff declining flu vaccination to provide a reason for their decline and staff working in 'higher-risk' environments to report declination decisions to their line managers.

The opt-out policy was difficult to implement and not well received by HCWs. The challenges experienced by vaccinators and managers were partly linked to the approaches to implementation of the policy and how the policy was communicated, rather than due to the policy itself. Most NHSTs tried to collect the personal details of staff alongside reasons for decline, and in some instances, these were recorded in Electronic Staff Records and reported to line-managers for action. These left some decliners feeling 'named and shamed' and created strain on employer-employee relationships.

To promote an opt-out approach effectively, there needs to be clear communication around the purpose of the policy, which should be to explore reasons for decline rather than identify and 'push' decliners to vaccinate, so as not to damage staff relationships. Engagement of staff and vaccinators in designing the policy is needed to ensure its acceptability, feasibility and effectiveness.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to express our gratitude to the participating NHS trusts and interview participants for their time and contribution to this research.

Funding

This work was funded by the National Institute for Health Research Health Protection Research Unit (NIHR HPRU) in Immunisation at the London School of Hygiene & Tropical Medicine in partnership with Public Health England (PHE) [Award letter refs: HPRU-2012-10096 dated 11th Dec 2013]. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health, Public Health England or of the London School of Hygiene & Tropical Medicine.

References

[1] Public Health England. H*ealthcare worker vaccination: clinical evidence (updated September 2018).* UK: Public Health England; 2018.
[2] Public Health England. Influenza: the green book, chapter 19; 2019. [Online]. Available at: https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 [accessed: 03.04.2020].
[3] World Health Organisation. How to implement seasonal influenza vaccination of health workers - An introduction manual for national immunization programme managers and policy makers. Geneva: World Health Organisation; 2019.
[4] Public Health England. Surveillance of influenza and other respiratory viruses in the UK Winter 2018 to 2019; 2019. [Online]. Available at: https://www.gov.uk/government/statistics/annual-flu-reports [accessed: 03.04.2020].
[5] Jorgensen P et al. How close are countries of the WHO European Region to achieving the goal of vaccinating 75% of key risk groups against influenza? Results from national surveys on seasonal influenza vaccination programmes, 2008/2009 to 2014/2015. Vaccine 2018;36(4):442–52.
[6] Public Health England. Seasonal flu vaccine data uptake amongst front-line care workers; 2019. [Online]. Available at: https://www.gov.uk/government/statistics/seasonal-flu-vaccine-uptake-in-healthcare-workers-winter-2018-to-2019 [accessed: 03.04.2020].
[7] Department of Health & Social Care. Government Response to the House of Commons Science and Technology Committee Report on Flu Vaccination in England: Ninth Report of Session 2017–19. London: Department of Health & Social Care; 2019.
[8] Stead M et al. Mandatory policies for influenza vaccination: Views of managers and healthcare workers in England. Vaccine 2019;37(1):65–75.
[9] NICE. Flu vaccination: increasing uptake; 2018. [Online]. Available at: https://www.nice.org.uk/guidance/ng103/resources/flu-vaccination-increasing-uptake-pdf-66141536272837 [accessed: 01.09.2019].
[10] Ribner B et al. Use of a mandatory declination form in a program for influenza vaccination of healthcare workers. Infect Control Hosp Epidemiol 2015;29(4):302–8.
[11] Polgreen P et al. Elements of influenza vaccination programs that predict higher vaccination rates: results of an emerging infections network survey. Clin Infect Dis 2008;46(1):14–9.
[12] LaVela S et al. Healthcare worker influenza declination form program. Am J Infect Control 2015;43(6):624–8.
[13] Lytras T et al. Interventions to increase seasonal influenza vaccine coverage in healthcare workers: A systematic review and meta-regression analysis. Human Vacc Immunotherap 2016;12(3):671–81.
[14] Polygreen P et al. Relationship of influenza vaccination declination statements and influenza vaccination rates for healthcare workers in 22 US hospitals. Infect Control Hosp Epidemiol 2008;29(7):675–7.
[15] Weinstein R, Talbot T. Do declination statements increase health care worker influenza vaccination rates? Clin Infect Dis 2009;49(5):773–9.
[16] Pless A et al. Nurses' attitudes towards enforced measures to increase influenza vaccination: A qualitative study. Influenza Other Respir Viruses 2016;11(3):247–53.

[17] Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Res Psychol 2006;3:77–101.
[18] Pearson M, Bridges C, Harper S. Influenza vaccination of health-care personnel, Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report 2006;55:RR-2.
[19] Talbot T et al. Revised SHEA Position Paper: influenza vaccination of healthcare personnel. Infect Control Hosp Epidemiol 2010;31:987–95.
[20] Department of Health. Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers; 2007. [Online]. Available at: https://www.gov.uk/government/publications/new-healthcare-workers-clearance-for-hepatitis-b-and-c-tb-hiv [accessed: 05.09.2019].
[21] Committee on Infectious Diseases. Influenza immunization for all health care personnel: keep it mandatory. Pediatrics 2015;136(4).
[22] Lukich N, Kekewich M, Roth V. Should influenza vaccination be mandatory for healthcare workers? Healthcare Manage Forum 2018;31(5):214–7.
[23] Van Delden J et al. The ethics of mandatory vaccination against influenza for health care workers. Vaccine 2008;26(44):5562–6.
[24] Thaler R, Sunstein C. Nudge. New Haven, CT: Yale University Press; 2008.
[25] Chen F, Stevens R. Applying lessons from behavioral economics to increase flu vaccination rates. Health Promot Int 2017;32:1067–73.
[26] Gerend M, Shepherd J, Monday K. Behavioral frequency moderates the effects of message framing on HPV vaccine acceptability. Ann Behav Med 2008;35(2):221–9.
[27] Nan X, Xie B, Madden K. Acceptability of the H1N1 vaccine among older adults: the interplay of message framing and perceived vaccine safety and efficacy. Health Commun 2011;27(6):559–68.
[28] Betsch C, Böhm Robert, Korn L. Inviting free-riders or appealing to prosocial behavior? Game-theoretical reflections on communicating herd immunity in vaccine advocacy. Health Psychol 2013;32(9):978–85.
[29] Mounier-Jack S et al. Organisational factors affecting performance in delivering influenza vaccination to staff in NHS Acute Hospital Trusts in England: A qualitative study. Vaccine. 2020;38(15):3079–85.
[30] Witteman H. Addressing vaccine hesitancy with values. Pediatrics 2015;136(2):215–7.
[31] MacDonald N, Butler R, Dubé E. Addressing barriers to vaccine acceptance: an overview. Human Vacc Immunotherap 2017;14(1):218–24.