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Title

Double-checking in the safe administration of medicines: Policy and practice in English hospitals.

Introduction

Medication errors are a leading cause of avoidable harm in healthcare systems globally [1]. Medication errors are estimated to contribute to or cause around 12,000 deaths per year in the National Health Service (NHS) and add £0.75-1.5 billion to healthcare expenditure [2]. Of around 237 million medication errors that occur every year in England, over half occur during the administration of medicines [3]. Although most medication errors (72%) result in no harm, 66 million are 'potentially clinically significant.' A medication administration error (MAE) can be defined as a 'deviation from the prescriber's medication order as written on the patient's charts or relevant administration instructions'[4]. MAE rates vary by route with 5.6% of oral and 35% of intravenous administrations, respectively, erroneous[5]. Medication administration is a complex process, comprising several steps that include counting, calculating, measuring, mixing and ensuring that the right patient receives the right dose, at the right time, via the right route, for the right reason[6].

To prevent MAEs, various strategies have been introduced into hospital care such as technological support systems, training, distraction reduction techniques, checklists and interruption management techniques such as 'quiet zones' and 'do not disturb' tabards for medication preparation [7-8]. Independent double-checking of medicines is one of the most frequently used strategies to prevent MAEs [7,9]. It is also used to prevent diversion of controlled drugs, such as opioids and benzodiazepines, which are subject to legal regulations given their potential for misuse. This practice involves two healthcare professionals, usually nurses, separately checking a medicine, before it is administered to the patient[10]. Double-

checking builds redundancy into the medication administration process by duplicating critical tasks and is underpinned by the premise that human error can be minimised by another person's compensatory behaviour[11-12]. Despite the intuitive appeal and prevalence of this strategy, a systematic review in 2020 found insufficient evidence that double-checking reduced the rate of MAEs[13]. Most of the 13 included studies were of poor quality. Of the three good quality studies, one showed a significant association between double-checking and reduced MAEs, another showed no association, and the third study reported only adherence rates. These findings align with a recent systematic review examining the effectiveness of double-checking in high-risk industries (chemical and aviation) and which reported no improvement in error detection when two people were involved in checking[14].

Previous research has provided possible explanations as to why double-checking may be ineffective. It is a task that requires attentional resources but simultaneously is repeated frequently in the same context (i.e., becomes habitual). This means that, over time, the task commands less attentional resource and becomes automatic[15]. Further to the automaticity of double-checking, the task is also hampered by a tendency to defer to authority, the diffusion of responsibility, social loafing and repeated distractions and interruptions[16-19]. Such problems are even more likely when double-checking is primed (where one nurse shares information with another which may influence the checking nurse), rather than being independent, with previous studies finding independent double-checking to be rare[20]. Such deviations from policy have been purported to contribute to medication administration errors[4].

Double-checking, whether performed independently or not, is time-consuming and resource intensive. An Australian study conducted observations of 5,140 medication administrations to paediatric inpatients and, of these, 69% required a double-check according to hospital policy. Each double-check took on average 6.4 minutes. The authors applied these

results to the estimated 1800 medication doses administered each day in the hospital to calculate that double-checking was consuming 133 nurse hours per day (equating to an estimated annual cost of approximately £1.3 million for one 340-bed paediatric hospital). Pronovost et al[21] reported that time spent double-checking in one US intensive care unit (ICU) was equivalent to one full-time nurse. If double-checking were effective at reducing MAEs, these resources could be justified, however, no such evidence exists. In fact, studies have found that not only does double-checking potentially waste staff time, but it can also harm patients by delaying administration of critical medicines[22-23].

Historical evidence for how double-checking became established in UK practice is not easily available; indeed, the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (the former nursing and midwifery regulatory body) and, more recently, the Royal College of Nursing asserted there is no regulatory requirement for double-checking except for medicines that require complex calculations[24]. Despite this, we understand that many hospital trusts have assimilated double-checking over the past 25-30 years in response to recommendations from the investigation of MAEs. However, to our knowledge, there is currently no national picture in England of i) the extent to which organisational policies stipulate double-checking, ii) the variation in double-checking policy or iii) how closely double-checking is perceived to be conducted in accordance with policies.

Therefore, this study aimed to understand the extent to which current medicines administration policies in English hospital care stipulate double-checking and how closely these double-checking policies are perceived to be adhered to in practice. The term ‘hospital care’ in the context of this paper refers to comprehensive medical services provided to patients in a hospital setting i.e. not care provided in primary (e.g. GP practice), community (e.g. outpatient clinics) or tertiary settings (e.g. highly specialist treatment such as neurosurgery).”

Methods

Two separate forms of data collection were employed. First, an online survey and second, Freedom of Information requests.

Sampling and recruitment

From September to October 2023, invitations containing a link to an online survey were emailed to members of a national network of all the Medication Safety Officers (MSOs) in England (N=400). The survey was distributed only to MSOs based at acute NHS Trusts (N =123, 31%). This network was selected due to an existing relationship with the research team and a demonstrated interest in participating in healthcare services research. Additionally, Freedom of Information (FOI) requests were made to 118 English NHS acute hospital trusts on 26th September 2023 for policies underpinning medicines administration e.g. general medicines policies and specific policies, such as intravenous and paediatric medicines. An NHS trust is an organisation within the NHS that provides healthcare services[25]. Acute NHS Trusts focus on providing short-term, hospital-based treatment for patients with acute illnesses or injuries and is the setting in which most double-checking of medicines happens in healthcare in England. A list of all English NHS acute hospitals was generated using the 'NHS Provider Directory' website.

Survey design

The survey, designed using Qualtrics®, included open-ended and multiple-choice questions. It comprised ten questions (Appendix 1) focusing on participants' perception of how double-checking is conducted in practice and how closely it follows Trust policy. The survey was developed in consultation with a pharmacist (DPA) and piloted with two MSOs. An MSO is an individual within an NHS organisation responsible for encouraging medication incident reporting and learning. Often, MSOs have a background in pharmacy[26]. MSOs were the

target population for this survey because they are responsible for supporting all Trust staff with the safe use of medicines and so are familiar with policies underpinning medicines administration.

Policy Data Extraction Tool

A data extraction Excel® spreadsheet was developed to capture policy details relevant to the research questions (Appendix 2). To determine the data extraction points of this spreadsheet, DH and HH familiarised themselves with the double-checking sections of policies by carefully reading a random selection and identifying common features. Additionally, previous evidence detailing common features of double-checking policies were used to inform these data extraction points[13,16,27]. The eighteen selected data extraction points focused on different groups of medicines requiring double-checking and the level of detail that policies provided when describing the double-checking process. The spreadsheet was piloted with FW (a hospital pharmacist) and modified following feedback.

Ethics

Using the Health Research Authority online decision tool (https://www.hra-decisiontools.org.uk/research/), it was determined that formal ethical approval was not required for this study.

Data Analysis

Survey data

Microsoft Excel® was used to calculate frequencies of responses for the multiple-choice questions.

Medicines administration policies

DH and HS were each allocated half of the policies, from which they identified sections providing information relating to double-checking of medicines. This information was used to populate the data extraction spreadsheet (Appendix 2). In the case of uncertainty, discussion ensued until agreement was reached. Once data extraction was complete, FW extracted information from a random sample of 10% of the policies and discrepancies were discussed until consensus was reached.

Results

Survey data

Survey responses were received from 48 MSOs representing a 39% response rate.

Medicines administration policies

Policies were received from 94 acute NHS Trusts (80% response rate). We were able to extract relevant information from 82 of these policies. The analysis will focus only on these 82 policies. The length of documents ranged considerably with additional appendices attached and/or linked to some policies, some of which we did not receive from Trusts.

1. Do acute NHS hospital trust policies stipulate double-checking, in what circumstances and for which medicines?

All policies required double-checking for some or all types of controlled drugs. The majority of policies (N = 63, 77%) stipulated double-checking of intravenous medicines and 38 (46%) also required double-checking of medicines administered by other parenteral routes, most commonly referring to intramuscular and subcutaneous administration and grouping them, alongside intravenous, under the term ‘injectable medicines’. However, there was some variation between trusts in the specific medicines which were exceptions to these rules and only required a single-check. For example, two policies (2%) required all injectable

144 medicines apart from prophylactic doses of sub-cutaneous low molecular weight heparins to
145 be double-checked. Sixty-four (78%) policies stated that all medicines administered to
146 children and neonates required a double-check. Trust definitions of the 'under 18' patient
147 group varied considerably; some specified an age group e.g. 'under 12s,' whilst others simply
148 described it as 'children and neonates'. Sixty-four policies (78%) stipulated that medicines
149 requiring a complex calculation must be double-checked, although what was meant by
150 'complex' was infrequently defined. However, a small number provided more detail, e.g.,
151 specifying that a complex calculation comprises a dose calculated using body surface area or
152 patient's condition.
153 Forty-eight policies (59%) stipulated that either chemotherapy drugs or cytotoxic medicines
154 should be double-checked, with a small number of policies excluding oral cytotoxics from
155 double-checking. Policies varied greatly in their instructions on insulin administration. In
156 57% (N=47) policies, insulin was not mentioned specifically; however, double-checking of
157 this medicine was encapsulated by the 'injectable medicines' category. Some stated that all
158 forms and routes of insulin must be double-checked by a second practitioner, whilst some
159 permitted the patient, where appropriate, to act as second checker for subcutaneous insulin.
160 Other policies specified that only insulin administered using a vial required double-checking.
161 Thirty-one policies (38%) specified that 'intravenous fluids' or 'intravenous preparations'
162 needed to be double-checked. Four policies (5%) stated that nurses should conduct a double-
163 check if they were administering an unfamiliar medicine. Table 1 presents the medicine
164 groups for which policies stipulated double-checking across all 82 Trusts.
165

166 **Table 1. Percentage of Trusts whose policy stipulated a double-check for specific**
167 **medicine groups.**

Medicine Group	Number of Policies	Percentage of Trusts
DC stipulated for at least one type of medicine	82	100%
Controlled drugs	82	100%
Complex Calculation	64	78%
Children	64	78%
IV medicines	63	77%
Cytotoxic medicines	48	59%
Injectable medicines	38	46%
Intravenous fluids	31	38%

2. Do policies describe how double-checking should be conducted (e.g., independent double-checking

When describing how a double-check should be carried out, most Trust policies (N=53, 65%) referred to one or more of the 'Five Rights of Administration' (i.e., right patient, medicine, dose, time, route) but would state that two registered practitioners must check each of these details prior to administration. Sixty-three percent (N=52) of all policies mentioned that the double-check must be conducted independently. Only 26% (N=21) of all policies provided further detail on either how to conduct a double-check or the importance of conducting the check independently e.g. "*When a second person is asked to check a calculation, they must… not confirm the first person's answer until after they have performed the calculation."*

3. Do MSOs think that double-checking practice aligns with policy?

In response to the question 'In practice, how closely do you think the checking of medications adheres to the policy/ies in your Trust?', the most frequently selected answer was 'some of the time' (33%). Twenty-nine percent selected 'most of the time' and six percent selected 'rarely.' Six percent selected 'unsure' and only 4% of responses indicated that it is 'always' carried out in accordance with practice. Twenty-one percent did not answer the question.

In response to open-ended survey questions asking participants to provide further information in relation to their quantitative responses, five provided explanations that alluded to some of the reasons why healthcare staff do not adhere to double-checking policy (Table 2).

207 **Table 2. Perceptions of how closely double-checking is conducted in accordance with**

208 **policy**

Participant number	Participant quotation	Summary
1	*"Think pharmacy staff are very methodical so process of independent second checking comes naturally to them. We do it in dispensaries and aseptic routinely. I don't think nurses always have the same processes. If the second checker is to be really accountable for their second check then they should also sign EPMA MAR (*Electronic Prescribing and Medicines Administration Medicines Administration Record*) – this is more time consuming and logistically difficult when they need to sign EPMA MAR. If it is mandatory then one nurse can't give without a second which could cause delays. Our nursing staff feel that they can't support a mandated second check as it would be too time consuming having to log in etc."*	Time pressure and challenges to accessing electronic health record systems
8	*"Would be helpful to have more national guidance on this topic. Introduction of new nursing roles has also added to the complexity".*	Wishes for clarity
10	*"Concerns over framing bias and that each person relies more on the other person's check than their own which causes a false sense of security. I believe that single checks are safer and more efficient."*	False sense of security

1	*“I don’t think it is well understood that an independent second check needs to be against the prescription not just against what nurse 1 tells you their patient needs. We have done a lot of work across the organisation to try to get this message across."*	Knowledge barrier
10	*Administrating staff do second check as per policy but I don't think the checks are independent and free from framing bias. I think there will be a lot of practice where the first person says "can you check this morphine?" rather than "what is this?". So, the action takes place but the method is not safe.*	Framing bias
22	*“I would like to see an introduction of single check IV for pre prepared products, so the focus can be on an independent check of higher risk drugs/ additives etc and be taken more seriously in line with the increased risks”*	Selective double-checking to improve quality
28	*"It is getting much harder due to staffing for double checks to be carried out and it may be that the checks are less detailed than they should be and cover the items to be prepared not the actual admin or rate of pump. Staff are much less experienced than 5-10 yes ago and since covid there has been less experienced teaching the inexperienced.”*	Lack of experienced staff
28	*“Feel that the competency and the detail being taught at university needs to be reviewed as there is a gap between*	Training and practice gap

	what is taught and what we would think/ assume is taught. Would also welcome the process of training being reviewed nationally."	

Discussion

This study explored the extent to which medicine administration polices stipulate double-checking, the variation in double-checking policy between NHS Trusts in England and how closely double-checking is carried out in accordance with policy as perceived by local MSOs. The findings demonstrate that double-checking policies vary considerably between Trusts and that MSOs perceived that it is common, in practice, for double-checking not to be conducted in accordance with policy.

All reviewed Trust policies required double-checking for controlled drugs. Further to this, many required double-checking for specific medicines or in particular circumstances. Most commonly, these were intravenous medicines, medicines administered to children, medicines requiring complex calculations and cytotoxic/chemotherapy medicines. However, policies varied considerably around administration of injectable medicines and insulin to adults. A minority of policies specified that 'intravenous fluids' needed to be double-checked. Most policies provided no detail on how to conduct a double-check or the importance of conducting the check independently. There was also a great deal of variation between Trust policies in the medicines exempt from double-checking requirements.

This variation between local medicine administration policies suggests a lack of clear, robust guidance underpinning how and when double-checking should be conducted. A possible explanation for this variation is that, at an organisational level, double-checking policies have evolved in response to local MAEs. For example, in response to an error involving administration of IV fluid, a local policy adds IV fluids to the list of medicines

requiring a double-check to prevent future errors. In this way, well-intentioned changes to policy can be made based on local circumstances rather than evidence. Dixon-Woods[28] refers to this as the 'lovely baby' syndrome where formal evaluation is sidestepped because improvement efforts appear so intuitive that it is assumed they work.

Despite the lack of evidence that double-checking prevents MAEs, it may serve an alternative function that provides value at a different level of the healthcare organisation. For example, Schwappach et al[12] reported that nurses felt reassured by co-workers checking the prepared medications prior to administration because it reduces the burden of responsibility. Therefore, although double-checking may not provide direct benefits for patient safety, it may improve nurse well-being by providing emotional support. Emotional support is essential for healthcare staff well-being which has been linked to better patient safety outcomes. Therefore, it is important to be aware of the wider safety implications and potentially hidden functions that double-checking may serve[29-30].

The survey finding that most respondents perceived double-checking to be conducted in accordance with policy 'some of the time' supports existing literature demonstrating that double-checking is often not conducted in accordance with policy[20,22,31]. A few participants shed light on why this is the case, e.g. pragmatic reasons including inadequate staffing and insufficient time. Such barriers have been identified in previous studies examining the value of double-checking[12,16,31]. Other participants alluded to the fact that, despite Trust policies stipulating independent double-checking, it was often primed by another nurse, introducing framing bias. With only 26% of the reviewed policies providing detail on either how to conduct an independent double-check or the importance of conducting the check independently, it is possible that this misalignment between policy and practice could be explained by double-checking policies not being detailed or clear enough[32].

An alternative explanation for the finding that, most participants perceived double-

checking to be conducted in accordance with policy only 'some of the time' could be due to nurses being selective in when they choose to adhere to policy, based on a case-by-case evaluation of the value it adds. Schutijser et al[22] reported that, across two Dutch hospitals, nurses based their decision on how closely they adhered to double-checking policy on the vulnerability of the patient and how familiar they were with administering the medicine. Nurses thereby used their critical judgement to only double-check in accordance with policy when they perceived the risk of medication error to be high. Similarly, Westbrook et al[20] found that nurses commonly double-checked even in circumstances when the practice was not mandated.

To our knowledge, this is the first study to review double-checking policies specifically across English NHS Trusts. We identified variation in double-checking policies between Trusts and in how closely double-checking is conducted in accordance with policy as perceived by MSOs. It is important to note that, although MSOs provide support to all Trust staff on the safe handling of medicines, conducting double-checking is not part of their role and so future research should seek to capture nurse perceptions of how closely double-checking adheres to policy. Another limitation of this study is the possibility that some Trusts only shared a subset of the policy documents requested, to reduce the administrative burden for FOI respondents[33]. Future research may benefit from using a multi-pronged approach to access Trust policies to reduce the likelihood of missing documents.

In conclusion, the variation between policies identified by the present study might also reflect a lack of robust evidence underpinning the practice of double-checking. Research is needed to understand if double-checking is effective at preventing medication errors and, if it is, the exact circumstances in which it is effective, to facilitate the standardisation of double-checking policies. Identifying circumstances in which double-checking is ineffective

may lead to the removal of some existing policies which could reduce nurse workload and free up time for patient-focused care.