Automatic dispensing cabinets and governance of controlled drugs: an exploratory study in an intensive care unit

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ABSTRACT
Background Governance of controlled drugs (CDs) in hospitals is resource intensive but important for patient safety and policy compliance.
Objectives To explore whether and how storing CDs in an automated dispensing cabinet (ADC) in a children’s hospital intensive care unit (ICU) contributes to the effectiveness and efficiency of CD governance.
Methods We conducted a mixed-methods exploratory study, comprising observations, interviews and audits, 3 months after ADC implementation. We observed 54 hours of medications activities in the ICU medication room (with 42 hours of timed data); interviewed nurses (n=19), management (n=1) and pharmacy staff (n=3); reviewed 6 months of ICU incident reports pertaining to CD governance; audited 6 months of CD register data and extracted logs of all ADC transactions for the 3 months following implementation. Data analysis focused on four main CD governance activities: safekeeping/controlling access, documenting use, monitoring, and reporting/investigating.
Results Nurses and pharmacists perceived spending less time on CD governance tasks with the ADC. The ADC supported CD governance through automated documentation of CD transactions; ‘blind counts’; automated count discrepancy checks; electronic alerts and reporting functionalities. It changed quality and distribution of governance tasks, such as removing the requirement for ‘nurses with keys’ to access CDs, and allowing pharmacists to generate reports remotely, rather than reviewing registers on the ward. For CDs in the ADC, auditing and monitoring appeared to be ongoing rather than periodic. Such changes appeared to create positive reinforcing loops. However, the ADC also created challenges for CD governance. Most importantly, it was not suitable for all CDs, leading to workarounds and parallel use of a safe plus paper registers.
Conclusions ADCs can significantly alter CDs governance in clinical areas. Effects of an ADC on efficiency and effectiveness of governance tasks appear to be complex, going beyond simple time savings or more stringent controls.

BACKGROUND
Effective governance of controlled drugs (CDs) in hospitals is necessary for the safety of staff and patients, compliance with the law, and CD stewardship. We define CD governance in hospitals as the structures and processes to organise, secure, monitor and account for, supply and use of CDs. CD governance may involve trade-offs (such as making CDs more secure but less accessible in emergencies), and may result in limitations, such as error-prone, time-consuming record keeping via paper-based systems. CD governance may particularly affect clinical areas with high use of CDs, such as intensive care units (ICUs).

Automated dispensing cabinets (ADCs) have been introduced in hospital wards to make CD governance more effective and efficient. However, evidence on the effects of ADCs on CD governance is limited, as most research on ADCs implementations is not focused specifically on CDs or their impact on CD governance. A few studies suggest that ADCs save nurses or pharmacists’ time on CDs governance, for example, due to the elimination of (some or all of) the daily counts of CDs, or because of less time spent updating paper registers. Reports of initiatives to identify CD diversion in US hospital show how ADC may contribute to monitoring and investigations. However, the literature also suggests that issues remain with CD governance after ADC implementations.

We aimed to explore whether and how an ADC contributes to the effectiveness and efficiency of governance of CDs and through what mechanisms.

METHODS
We carried out an exploratory, mixed-methods study of an ADC in a paediatric ICU, with a focus on CDs.

The setting
The study was conducted in a children’s hospital in Sydney, Australia. The hospital implemented an ADC (Omnicell®) in the ICU on 26 March 2019.

Study design
We applied both quantitative methods (structured observations, audits of registers and data extracted from ADC) and qualitative methods (unstructured observations, interviews, reviews of incident reports). The audits were able to capture CD governance data before and after ADC implementation retrospectively, while the other methods were limited to a post-implementation period. We considered medications as CDs if they were treated as such on the ICU concerned for the purpose of governance.

Observations
Observations, structured and unstructured, were carried out by one researcher (VL) in the ICU medication room about 3 months after ADC implementation (June–July 2019). All activities carried...
out in the medication room were included. Structured observations were recorded using the Work Observation Method By Activity Timing (WOMBAT 3.0) tool, which automatically timestamped recorded data. Unstructured observations were captured as field notes. ADC training sessions, where nurses received training as ‘super users’, were also observed.

Interviews
Qualitative semi-structured interviews were conducted by one researcher (VL) with ICU nurses to gather their perceptions and experiences with using the ADC. All nurses present on the ward on the interview days were invited to participate and could do so individually or as a group. We also sought to interview pharmacy staff, implementation team and hospital management for their views. Sampling was purposive. With consent, interviews were audio-recorded and transcribed; otherwise, the researcher took concurrent field notes.

Incidents
We (VL, PG) carried out a retrospective review of patient safety incidents voluntarily reported through the hospital incident reporting system. All ICU incident reports relating to medications for a period of about 3 months before and 3 months after ADC implementation (January–June 2019) were reviewed.

Audits of controlled drugs registers and ADC transaction logs
Retrospective audits of entries documented in ICU CD paper registers, about 3 months before and 3 months after ADC implementation (January–June 2019) were carried out by two researchers (VL, PG). As a control, we also audited registers from the oncology and orthopaedics wards.

Data extracted from the registers included: date and time; drug name, strength, formulation; amounts (received, given, discarded, balanced); discrepancies (box 1) identified by staff as annotated in registers and number of asterisks to signal amendments to records. We also captured missing amounts. For the denominator, we recorded the number of CD doses administered or discarded.

Two researchers (MR, VL) conducted a retrospective audit of all transactions recorded by the ADC for 3 months following implementation (26 March–30 June 2019). Data extracted included: date and time; drug name, strength, formulation; transaction types (issue, return, waste, cycle count); amounts (issued, discarded, counted, returned) and discrepancies by type (eg, cycle count discrepancy).

Data analysis
The quantitative data analysis was conducted using descriptive statistics in SPSS (V.23) for the WOMBAT data and Excel for the audit data. For the CD register data, we assessed number and frequency of CD discrepancies, calculation errors and other inaccuracies in documentation. The analysis was performed per ward, per type of medication (single doses vs multidose bottles), before and after ADC implementation and as a comparison across wards. For the ADC transaction logs, we calculated the number of ADC-generated discrepancies and time to resolution of discrepancies. For all transactions of CDs removed from the ADC, we matched the corresponding ‘partial waste’ data and calculated time to waste (the time from removing a medication dose from the ADC and documenting partial waste). For the WOMBAT data, we mapped the corresponding ADC transaction log data to obtain details about the type of medication (CD or non-CD) involved in the recorded activities and calculated frequency and duration of activities for each medication type.

Qualitative data from field notes and interview transcripts were first coded inductively by one researcher (VL) using NVivo (V.12) to capture aspects related to systems (eg, ADC, safe and registers), medications (CDs and non-CDs), activities and participants’ views as well as the wider context of ICU medication work. Incidents were also analysed thematically in a spreadsheet. Initial analysis was then independently verified by two researchers (MP and PG), with disagreements discussed and resolved via consensus. We then focused the analysis on CD governance. We identified four main activities of CD governance (table 1) in the data and local/national policy and used this as a framework to analyse mechanisms supporting or hindering CD governance, integrating qualitative and quantitative data within this framework.

RESULTS
Table 2 provides details of the data included in the study. We structure the findings around the main governance activities described in table 1. The focus is on the use of ADC for these activities, compared with a safe plus registers when appropriate. Table 3 provides a summary of the findings.

Safekeeping and controlling access
Prior to ADC implementation, CDs were kept in a locked safe, with CDs in need of refrigeration kept in an unlocked fridge. CD supply and use were documented in paper registers (‘CD books’).

The ADC was implemented in a new locked medication room created in the ICU, accessible with personal smartcards. Only registered staff members could access the ADC, by fingerprint or individual username and password. CDs were stored in the ADC in drawers which required the fingerprints of two authorised staff for access. However, some CDs could not be stored in the ADC (CDs belonging to patients, those to be discarded and liquid CDs in multidose bottles). Thus, a safe was also placed in the medication room, to store these CDs, leading to parallel use of ADC plus safe for storing CDs. The safe was also needed in case of ADC breakdown.

One CD (clozapam liquid) that needed to be refrigerated was stored in the ADC fridge. The fridge was locked but did not require two fingerprints for opening, thus technically this CD
could be accessed by any authorised user accessing the ADC fridge without a witness. Transactions of the CD in the fridge had to be recorded in paper registers. This required a workaround on the ADC that created potential for errors, as shown in a reported incident (Id7). However, this was considered an improvement on previous storage arrangements, as the ADC provided a level of controlled access that was previously absent.

... now is better in the sense that the fridge is locked. [Before the ADC], [...] if [the CD] needed to be in a fridge it would just be in the fridge [...], there was no real, a way to do it, we’ve got ways to do it now which is exciting. (id4)

Access to the safe required a key, usually held by senior nurses (known locally as ‘access nurses’). However, other nurses held the key when the access nurse was away or busy. Nurses reported finding the keys to the safe as time consuming and delaying access to medications for patients. The ADC removed the need for keys and for the presence of specific staff members—any authorised nurse and witness were sufficient to access CDs in the ADC.

However, the ADC only allowed one transaction at a time, while CDs in the safe could be accessed by multiple nurses at the same time. Some nurses reported having to wait to access medications in the ADC, when in use. However, we observed nurses queuing to access the ADC rarely (online supplemental appendix 1). In addition, it was possible (and observed) for a nurse to access the ADC when a previous user had not ‘exited’ the transaction and therefore to use their login.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Activities for the governance of controlled drugs (CDs) in hospital wards</th>
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<tbody>
<tr>
<td>CD governance activity</td>
<td>Description</td>
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</table>
| Safekeeping/Controlling access | ▶ CDs (including those owned by patients) stored separately from other medications, in a cabinet or metal safe, kept locked when not in use.  
▶ Access to CD cabinets’ keys strictly controlled.  
▶ Access to CD cabinets restricted to staff members authorised to administer them.  
▶ Accesses witnessed by a staff member.  
▶ Expired, unusable or unwanted CDs stored in the safe pending destruction. |
| Documenting transactions | ▶ Records kept of CD transactions in a drug registry.  
▶ Records of transactions signed by two staff members present during the activity (eg, nurse and witness).  
▶ Transactions recorded in the CD register included: removal and replacing of CDs from the storage unit; discarding any unused portion of the CD and destruction of CDs. |
| Monitoring | ▶ Audits of CDs in stock performed to confirm records are meeting policy requirements and to detect any possible misappropriation.  
▶ The recorded CDs balance checked daily against the physical balance in the cabinet and safe, by a registered nurse/midwife with a witness and documented in the register.  
▶ Expired, unusable or unwanted CDs, pending destruction, are included in the routine stock checks. |
| Reporting and investigating | ▶ CDs discrepancies recorded and reported to the hospital management and authorities.  
▶ Investigations conducted to explain the discrepancies. |

**Documenting use**

Removing (or returning) CDs from (or to) the ADC required entering data in the ADC documenting both transaction and remaining levels of stock. The ADC automatically recorded date, time and staff members involved (through their fingerprints), as well as the patient name, prescriber name and the CD as selected on screen. Additional data entry was required to add any discarded amounts, and remaining levels of stock. In contrast, a CD could be removed from the safe but documentation in the paper register could be delayed and possibly forgotten.

In case of incorrect data entry of remaining stock levels, the ADC alerted the users by inviting a recount, thus contributing to preventing discrepancies due to counting errors.

If you happen to put in like fentanyl 30 and there’s 29 … It actually alerts you. [...] previously you would have just read 30 and three days later someone would have picked it up. [...] this way, I think, it prevents those kinds of incidents (id6-9)

We found that removing a CD from the ADC (also including, when necessary, preparing the medication for administration) took two nurses between ~1 min (66 s) and ~12 min (748 s); the corresponding task performed with the safe and registry took from ~1.5 min (98 s) to ~8 min (472 s) (table 4). However, nurses perceived removing and documenting CDs from the ADC to be less time consuming than with safe and registers.

<table>
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<th>Table 2</th>
<th>Overview of methods and data type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods and data type</td>
<td>Description</td>
</tr>
<tr>
<td>Ethnographic observations; field notes</td>
<td>About 54 hours of observations were completed over 14 days in the period 6 June–24 July 2019. Periods of observations were of 2 hours 30 min on average (min 1 hour to max 7 hours). Three one-to-one sessions of nurse ADC super-user training were also observed.</td>
</tr>
<tr>
<td>Timed observations with WOMBAT; structured tasks and time stamps in spreadsheet</td>
<td>About 42 hours of observations were timed using the WOMBAT tool. Timed observations took place over 13 days between 6 June and 24 July 2019, average duration of individual observation session: 2 hours 23 min (range 1–47 hours).</td>
</tr>
<tr>
<td>Interviews; transcripts of audio recordings and field notes</td>
<td>Two 2-hour drop-in sessions were organised to facilitate interviews with ICU nurses: 19 nurses participated. Interviews took place with ADC back-office pharmacist, ADC trainer, Deputy Director of Pharmacy, Clinical Program Director.</td>
</tr>
<tr>
<td>Incidents reports; structured and free text data in spreadsheet</td>
<td>We received a total of 171 incidents that had been reported in ICU in relation to medications in the period January–June 2019, 109 of these pertaining to use/supply/governance of CDs.</td>
</tr>
<tr>
<td>Audits of controlled drug registries; structured data in spreadsheet</td>
<td>We audited 6 CDs registers (1231 pages) in ICU, 5 registers (1120 pages) in oncology and 9 registers (1996 pages) in orthopaedics.</td>
</tr>
<tr>
<td>ADC transaction logs; structured data in spreadsheet</td>
<td>We received logs of all recorded ICU ADC transactions for the period March–June 2019.</td>
</tr>
</tbody>
</table>

ADC, automated dispensing cabinets; CDs, controlled drugs; ICU, intensive care unit; WOMBAT, Work Observation Method By Activity Timing (a structured data collection tool).
Compared with paper registers, the ADC restricted flexibility for amending records, such as documenting later discarded amounts, or returning an unused CD to the ADC. A workaround had to be devised for these tasks using the function ‘miscellaneous returns’. We observed how some nurses had difficulties completing these tasks on the ADC, and similarly they reported:

… when you’re taking [a CD], […] if you forget to enter the waste, […] in the book, there will be an empty space and then you might think of it. […] Even with ADC you have to come back sometimes, but sometimes you tend not to. Like it happened to me once, and then it’s a bit tricky […] I don’t know how to do that. (id10-13)

Analysis of the ADC transaction logs showed that for a total of 2632 CDs removed from the ADC, 64% had waste recorded (online supplemental appendix 2—table A) and 81% of these had waste recorded at the time of removing the medication. Comparable data for registers were not available.

Nurses reported daily counts of CDs stock to be faster with the ADC than with the safe and registers: ‘ridiculously quicker… So that’s really good’. (id6-9)

… [in CDs counts with the ADC] I feel that people actually check more than just writing the book up… … . (id4-20)

Nurses reported daily counts of CDs stock to be faster with the ADC than with the safe and registers: ‘ridiculously quicker… So that’s really good’. (id14-20)

… [with the books] you’ve got to write out every medication and everything. With [the ADC] you can just bang, bang, bang, fingers, and you go through and it’s done. It’s just so much quicker. (id21)

### Table 3: How an automated dispensing cabinet (ADC) may support or challenge governance of controlled drugs (CDs) in hospital wards

<table>
<thead>
<tr>
<th>CD governance activity</th>
<th>ADC support</th>
<th>ADC challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safekeeping/Controlling access</td>
<td>Access control by fingerprinting/username and password Double lock drawers (two users/fingerprints to access) No requirement for keys</td>
<td>Not all CDs ‘storable’ in the ADC. Parallel use of ADC and safe and registers required. Access to CD in the fridge only partially controlled, leading to a hybrid system of ADC for storage and paper registers for documentation. Workaround needed to give access to CD in the fridge and alert nurses of the different workflow. Parallel use of ADC by different users, for different transactions, not supported, leading to potential queues to access medications.</td>
</tr>
<tr>
<td>Documenting transactions</td>
<td>Documentation synchronous to removal/supply/count of CDs Automatically recorded data for most transactions, through fingerprinting and item selection on screen Automated alerts of potentially incorrect remaining stock balances recorded Users perception of efficiency and completeness of documentation</td>
<td>Reduced flexibility in amending records compared with paper. Returning CDs to the ADC more complex than with safe and registers.</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Counts of stock levels blind to documentation of balance Remote monitoring potentially in real-time, through reporting functionalities and remote access to ADC data Users perception of efficiency and greater control</td>
<td>Data recording only partially automated; some data entered by users may not be accurate (eg, reason for discarding a CD), thus affecting monitoring activities.</td>
</tr>
<tr>
<td>Reporting and investigating</td>
<td>Easier to identify discrepancies near the time of their occurrence, making it easier to investigate and resolve Investigations involving interviewing staff can be limited to staff that had access to the ADC in the period of interest</td>
<td>Access to CDs in the fridge by unregistered users (while others are still logged in), not detected by the ADC, is possible. Possible risk of illusion of completeness of records.</td>
</tr>
</tbody>
</table>

### Table 4: Time on specific tasks with controlled drugs (CDs) in the medication room, using automated dispensing cabinet (ADC) and safe with registers

<table>
<thead>
<tr>
<th>Time (s)</th>
<th>Number of tasks</th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADC</td>
<td>Issue</td>
<td>41</td>
<td>360</td>
<td>66</td>
<td>331</td>
</tr>
<tr>
<td></td>
<td>Return/Waste</td>
<td>1</td>
<td>108</td>
<td>108</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>Count</td>
<td>1</td>
<td>632</td>
<td>632</td>
<td>632</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>4</td>
<td>301</td>
<td>195</td>
<td>358</td>
</tr>
<tr>
<td>Safe</td>
<td>Issue</td>
<td>25</td>
<td>242</td>
<td>98</td>
<td>472</td>
</tr>
<tr>
<td></td>
<td>Return/Waste</td>
<td>0</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td></td>
<td>Count</td>
<td>2</td>
<td>483</td>
<td>469</td>
<td>496</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>2</td>
<td>225</td>
<td>48</td>
<td>401</td>
</tr>
<tr>
<td>Both ADC and safe</td>
<td>Issue</td>
<td>1</td>
<td>625</td>
<td>625</td>
<td>625</td>
</tr>
</tbody>
</table>

The data exclude tasks related to the CD in the fridge. Times presented in this table must be interpreted with caution. Samples are too small to be considered valid. Tasks performed with ADC are not directly comparable to the corresponding tasks performed with the safe and registries. The medications involved were different (unit doses in the ADC, bottles in the safe) and times of preparation may be significantly different for the different types of medication. The numbers of CDs stored in the ADC and safe were different—potentially affecting CD counts.
The ADC allowed pharmacy staff to monitor CDs in the ADC remotely by generating reports. For example, regular reports were generated on discrepancies with the CDs in the ADC. It also enabled monitoring from a distance that the CD counts had been done in the ward as expected.

... we have more real time reports. So every day at 10:00 am [the ADC] will look at the last 24 hours [...] and sends the ICU Manager a list of discrepancies generated on the ward for her to monitor. ... (id1)

**Reporting and investigating**

Discrepancies about CDs in the ADC were identified through daily reports and generally resolved within a day, as confirmed by transaction logs analysis (a range of 30s to 21 hours). Nurses had to document in the ADC a reason for rectifying a discrepancy, but usually entered a generic “error”.

Discrepancies with CDs in the safe tended to become apparent at the time of pharmacy audits or when the ward unexpectedly ran out of a CD otherwise documented as still available. Explaining these discrepancies involved reviewing all records since the bottle had been opened for any errors, and assessing whether the loss could be explained by dead space in syringes. Such losses could cumulate over large numbers of doses. The process was reported to be very time consuming for pharmacists.

In our audits, we found 54 discrepancies (losses or gains) for CDs in the safe, documented in CD registers in the ICU during a 6-month period (online supplemental appendix 2—table C). As staff told us, and our audits show, discrepancies were more frequent for medications in multidose liquids than for single doses.

The ADC could also be used to generate a list of those who had accessed the specific CD involved in a discrepancy, and thus limit investigations to these staff instead of questioning everyone on shift.

**DISCUSSION**

The ADC affected CD governance tasks in the ICU, through a variety of mechanisms. It afforded concurrent removal (or return) and documentation of CDs; it removed the need to control keys to a safe; afforded automated checks (eg, fingerprints) and electronic interaction with users (eg, questioning counts); and allowed real time, remote access to data (individual transactions and aggregate data) through the generation of reports. Nurses’ counts were ‘blind’ and nurses were found to ‘check more’ when counting remaining level of stock. Pharmacists monitored discrepancies remotely, rather than reviewing registers on the ward (or only doing the latter for CDs in the safe); auditing and monitoring was thus ongoing rather than periodic. These changes, combined, appeared to create positive reinforcing loops (figure 1).

However, the ADC only supported governance of CDs in single doses (eg, vials, tablets); a safe and registers were still needed for governance of other CDs. Workarounds were also needed to handle exceptions, such as the single refrigerated drug. Difficulties with the ADCs in relation to multidose liquids (not exclusively CDs) and refrigerated drugs have also been reported elsewhere.18

Nurses and pharmacists perceived CD governance to be more efficient with the ADC than with safe and registers. This is consistent with nurses’ perceptions and time and motion studies in other clinical contexts.10 18 19 27 We found the question on whether the ADC saves time on CD governance, compared with safe and registers, requires a nuanced answer. The ADC eliminated some time-consuming tasks...
When ADCs are in place.\textsuperscript{3} \textsuperscript{21} In the setting we studied, greater diversion occurred also beyond the ICU, to pharmacy and management dealing with CDs incidents, affecting their use of time. The ADC eliminated frustrating CD governance inefficiencies and this possibly led to perceived saving time.\textsuperscript{30}

The ADC made CDs safekeeping and access controls more stringent. In another setting, similar ADC technology was associated with fewer misappropriations of medications.\textsuperscript{13} However, the literature shows that diversion occurs also when ADCs are in place.\textsuperscript{12} In the setting we studied, greater quantities than prescribed could theoretically be removed from the ADC, not documented, and the refrigerated CD could be removed by any registered user accessing other medications in the fridge without a witness. Discarded CDs are also a recognized risk for diversion,\textsuperscript{3} \textsuperscript{9} especially in paediatric settings,\textsuperscript{21} which is not directly affected by use of an ADC or safe.

This study is unique in its focus on CD governance. Our analysis however did not include CD governance in prescribing or administration,\textsuperscript{3} as we did not observe these activities. We did not collect demographic data on the nurses who participated in the interviews; however, from the interviews it was clear that some were new to the ward, while others had senior roles. We were not able to compare the ADC to a baseline pre-implementation. We timed and compared tasks with ADC and safe, but our samples were too small to support significance testing.

CONCLUSION

Although creating new challenges, through varied mechanisms, an ADC has the potential to significantly alter CDs governance in clinical areas. But its effects on efficiency and effectiveness seem to be more nuanced and complex beyond merely producing time savings in governance tasks or more stringent controls.

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Contributors

VL conceived of the study, VL, BDF, MP and PG contributed to study design, MP provided specific input into the observational techniques, VL coordinated data collection and carried out observations and interviews, PG contributed to audits, VL led the analysis of the qualitative data, MP led the quantitative analysis. VL and PG analysed the incident reports. VL drafted the manuscript. All authors contributed to the interpretation of results and provided review and approval of the final manuscript.

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Disclaimer

The views expressed are those of the authors and not necessarily those of the funders, NHS, the NIHR or the Department of Health and Care.

Competing interests

None.

Ethics approval

The hospital research ethics committee approved the study. Interview participants gave written informed consent. ICU staff were informed that observations were taking place and an information poster placed near the medication room. Interviews, observation data and audits were anonymized at the point of data collection. Incidents and ADC log data were de-identified by the hospital prior to transfer to investigators.

Provenance and peer review

Not commissioned; externally peer reviewed.

Data availability statement

No data are available. Aggregate data that could be made available have been provided as tables in supplementary files. Our ethics and local approvals preclude making other data, such as interview data, publicly available.

Supplemental material

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