

# Quality improvement project to eliminate the occurrence of never events during insertion of intrauterine contraception

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## ABSTRACT

**Aim** This project aimed to reduce the occurrence of never events during insertion of intrauterine contraception (IUC), within Central North West London NHS Foundation Trust (CNWL) clinics, to zero within 6 weeks.

**Background** CNWL provides sexual health services in seven London boroughs and Surrey. Approximately 5500 IUC are inserted annually. Over a period of 67 days between 7 December 2017 and 12 February 2018, three incidents were identified within CNWL involving the insertion of an intrauterine contraceptive that was different to that agreed with the patient. Several different types of IUCs are available, avoiding insertion of an incorrect IUC device is important as it could lead to unwanted side effects and swapping to the chosen device could lead to a repeat procedure with potential increased risks of infection and uterine perforation.

Insertion of an incorrect IUC has been classified as a never event since January 2018 when NHS Improvement updated their never events list to include 'insertion of an IUC different from the one in the procedural plan'. Never events are serious incidents that are preventable if appropriate systems are in place. There is currently no national guidance on how to reduce the risk of IUC never events but since inclusion of IUC events in the never event list the Faculty of Sexual and Reproductive Health has been working to produce national guidance for safety standards for IUC insertion. In the interim, CNWL undertook a review of their local policies.

**Investigation and recommendations** Following the CNWL IUC never events, a root cause analysis investigation was conducted. A multidisciplinary team was convened to identify potential contributory factors. The main cause was identified as the lack of a standard process for confirming, documenting and double-checking the chosen IUC immediately prior to insertion. Other contributory factors included storage of similar IUC devices alongside each other and delayed access to a trained assistant in IUC clinics.

Quality improvement (QI) methodology was used to help implement local system changes to reduce the risk of future errors. These included changes to IUC storage and the introduction of an IUC checklist to confirm the chosen device type during IUC insertions.

**Results and conclusion** Since implementation of these changes 30 months ago there have been no further IUC never events within CNWL.

QI methods have facilitated the successful introduction of local system changes that have reduced the occurrence of errors during IUC insertion.

## AIM

This project aimed to reduce the occurrence of never events during insertion of intrauterine contraception (IUC), within Central North West London NHS Foundation Trust (CNWL) clinics, to zero within 6 weeks.

## PROBLEM AND BACKGROUND CNWL IUC incidents

CNWL provides sexual health services in seven London boroughs and Surrey. Approximately 5500 intrauterine contraceptives are inserted annually. Over a 67-day period between December 2017 and February 2018, three IUC never events occurred within CNWL. In two of the CNWL incidents, a non-hormonal copper IUC device (T Safe Cu 380 A) was inserted when the patient had agreed to a hormonal intrauterine device (Mirena). In the third incident, a standard sized copper IUC (TT 380 Slimline) was inserted when the patient had requested a smaller copper IUC (mini TT 380 Slimline). In all three incidents, the error was recognised immediately and the patient had same-day replacement of the device with the chosen device without any complications. Insertion of an incorrect IUC is important as it could lead to unwanted side effects and swapping to the chosen device could involve additional clinic visits and a repeat procedure with potential increased risks of infection and uterine perforation.

## Never events and national safety standards

Never events are defined in the National Health Service (NHS) as 'serious incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic barriers are available at a national level and should have been



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implemented by all healthcare providers'.<sup>1</sup> The never event list was updated in January 2018 to include 'implantation of an intrauterine contraceptive device different from the one in the procedural plan'.<sup>2</sup>

Earlier never event classifications did not include this separate clarification about IUCs.<sup>1,2</sup> There is limited data about the national frequency of IUC never events prior to January 2018. We anticipate that inclusion of IUC never events in the NHS Improvement never event list from January 2018 may result in a significant increase in national reporting of IUC related never events.

The National Safety Standards for Invasive Procedures<sup>3</sup> discusses safety standards for all invasive procedures including those taking place outside of operating theatres. Service providers are expected to produce local standards for all invasive procedures. There are currently no national standards that specifically address reducing the risk of IUC never events but the Clinical Standards Committee of the Faculty of Sexual & Reproductive Health is currently working to provide example guidance for local services.<sup>4</sup>

Review of the literature found no reports that specifically addressed processes to reduce the risk of IUC never events. However, there is good evidence from general surgery that insertion of the wrong implant/prosthesis within operating theatres is reduced following the introduction of WHO surgical checklist and implementation of local safety standards.<sup>3,5</sup>

### Local service standards

CNWL Sexual Health Services expanded in 2017, increasing its coverage to seven London boroughs and across Surrey, and taking on several hundred new staff who had been working to different local policies and standards within their previous trusts. There are approximately 75 staff who insert IUCs within the expanded service and insertions take place at 15 different clinic sites. During the same time, the service underwent significant reorganisation in response to changes in commissioning. The service recognised that having separate, unsettled teams, new to the organisation, spread across multiple sites were all factors that contributed to an increased risk of errors but felt that systems and processes could be improved to reduce these risks. Therefore, following the IUC never events in CNWL, a root cause analysis was conducted to identify contributory factors and areas for improvement.

### DESIGN

A multidisciplinary team was convened to conduct a root cause analysis to identify factors contributing to the occurrence of the never events (drivers) and to recommend corrective actions (change ideas) to prevent recurrence. As part of the analysis, representative staff from all aspects of the IUC process including ordering, stocking, inserting and assisting during IUC procedures were interviewed to establish their current practice and identify inconsistencies. Feedback was also gathered from the

patients involved in the never events. The IUC pathway was mapped in detail and the information gathered was reviewed in order to identify good and notable practice and any problems.

Contributory factors (drivers) were displayed as a driver diagram (figure 1).

This driver diagram is a pictorial image of all the potential drivers and change ideas that were discussed by the team. Not all change ideas were tested as part of this project; we prioritised the changes that the team felt would have the most impact.

The team concluded that the following drivers directly impacted on the never events:

#### Driver 1, the main cause

There was no standard process for confirming, documenting and double-checking the chosen IUC immediately prior to insertion.

#### Change idea 1

Introduction of an IUC checklist for use during all IUC insertions. The aim of the checklist was to standardise the process for confirming the chosen IUC and make clear the roles of the inserter, assistant and patient during the checking process (the checklist will be scanned and uploaded to the patient notes).

#### Driver 2

The storage of multiple similar IUC devices together (there are seven different IUCs on the CNWL formulary) increased the likelihood of the incorrect box being selected from the cupboard.

#### Change idea 2

The main storage areas in the procedure rooms to be stocked with only first-line IUC devices; other IUC devices to be in a separate storage area.

#### Driver 3

The lack of a readily available, trained assistant for IUC clinics meant staff had to wait for someone to become available, leading to loss of continuity, increased likelihood of staff becoming distracted (eg, due to involvement in other cases while waiting), increasing the risk of staff errors.

#### Change idea 3

All IUC clinics to have rapid access to a trained assistant.

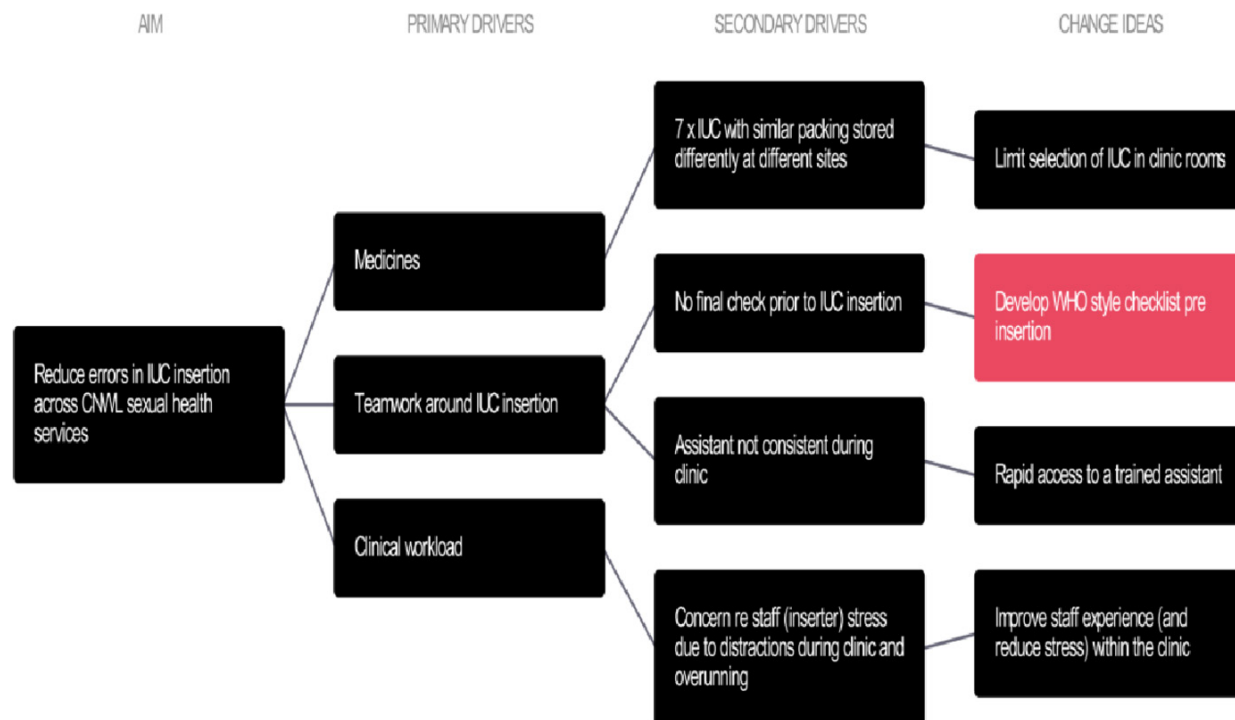
#### Driver 4

Staff distractions during clinic.

#### Drivers 3 and 4

They were explored as part of a separate quality improvement (QI) project and are not discussed further in this paper.

QI methodology was used to monitor delivery of the planned improvements.



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**Figure 1** Driver diagram.

## MEASUREMENT

### Outcome measure

The main outcome measure was the number of IUC never events. It was planned to display the occurrence of never events on a T chart. However, as there were no further events since initiation of the interventions there were not enough data points for a chart. So, the outcome measure has not been represented graphically.

### Process measures

Implementation of an IUC checklist just prior to IUC insertion was chosen as a key intervention. The process measure was an assessment of the percentage of IUC insertions that had a correctly completed checklist scanned into the patient record. This was assessed by review of a random selection of notes from 10 IUC insertions across all CNWL sites, initially at weekly intervals. This was displayed as a run chart ([figure 2](#)).

The second change idea taken forward was to rationalise the number of different types IUC device available and standardise their storage across sites. Achievement of this outcome was measured by introducing a new local policy on IUC choice and storage alongside spot checks at each site to confirm this policy was being followed.

## STRATEGY

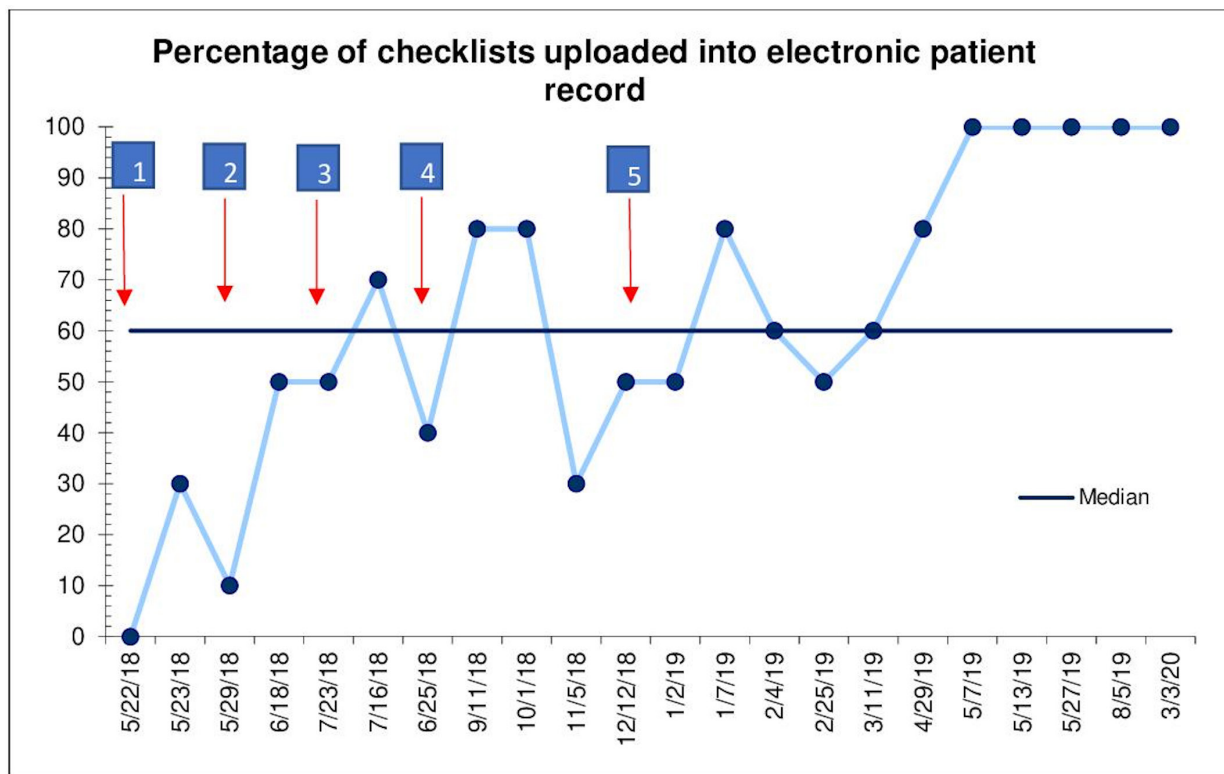
The implementation of the change ideas described in the section above is outlined below.

## IUC checklist

The first phase of implementation was to design a checklist and gain approval for its use by the staff. Following feedback from staff, the checklist was modified to avoid any duplication of information that was already collected elsewhere and yet still retain the ability to act as a failsafe checking process during the insertion procedure (online supplemental appendix 1). Consensus was then required to agree when and how the checklist was used and then how the checklist was stored in the clinical record. The acceptability of this process with staff and patients was checked prior to roll out. Staff team meetings were used to introduce the checklist to the wider staff group and the use of the checklist was monitored. Where use was not optimal, further staff training was provided via educational meetings, email and individual feedback. Incorporating the checklist into the patient electronic record was explored but it was felt essential to keep a hardcopy checklist so that this could be available by the bedside during the procedure. A process for administrative staff to scan checklists into the patient records after the procedure was developed. To ensure checklists were scanned into the notes, formal time was allocated to staff for this task. Once the process was successfully embedded into practice, ongoing intermittent ad hoc monitoring of sites was undertaken to ensure that the improvement was sustained.

## Changes to IUC storage

A representative group of clinicians and pharmacists met to discuss the number of devices included on the CNWL



### Interventions

1. Initial staff training on undertaking a checklist
2. Further staff training including educational meetings and individual feedback
3. Adapted scanning process
4. Individual training reiterating how to complete checklist
5. Dedicated staff allocated to scan in one service location

**Figure 2** Percentage of checklists uploaded into electronic patient record.

IUC formulary and to rationalise the number of device types available. The proposed changes to the formulary were discussed at staff meetings and comments were invited. IUC devices were categorised as first line and second line. Only three IUC devices were categorised as first line. To minimise the chance of selecting the incorrect IUC device, only first-line IUC devices were stored in the main medicines/equipment cupboards in the procedure rooms. The IUC policy was updated with the new information and storage in clinics was adapted in line with the new policy. Staff were informed of this change and compliance was confirmed by spot checks at each clinical site.

## RESULTS

### Outcome measure

Since introduction of the changes, outlined above, 30 months ago there have been no further IUC never events within CNWL.

This compares with the occurrence of 3 incidents within a 67 day period before the changes.

### Process measures

#### IUC checklist

Figure 2 shows the percentage of IUC insertions that had a correctly completed checklist scanned into the patient electronic record. The run chart shows overall compliance across all 15 sites with correct completion and scanning of the IUC checklist into the patient records. When the new process was initially introduced compliance varied significantly across sites, with 100% compliance at 10 of the sites but <50% compliance at 3 sites. The reasons for non-compliance varied from site to site, ranging from lack of access to document scanners to temporary staff having inadequate induction. We initially relied on email to inform staff but found that local staff meetings and individual feedback to non-compliant sites was more effective. The extra staff time to scan the checklists was

minimal as staff were already scanning other IUC-related papers into the electronic records.

### Storage of IUC

Spot checks confirmed 100% compliance with the new local IUC policy regarding use and storage of first-line and second-line devices.

### LESSONS AND LIMITATIONS

The project was successful in achieving the aim of reducing IUC never events to zero.

Full compliance with the changes to IUC storage was achieved quickly. However, implementation of the use of the IUC checklist, which involved much greater changes to daily practice, presented several challenges, mainly around embedding a new process across disparate staff groups spread across multiple sites with limited opportunities to meet face-to-face. We were careful to involve a wide range of staff from all disciplines throughout the process and to modify both the checklist and the process for scanning in response to their feedback. When implementing use of the checklist, we found our initial approach of disseminating information at large multidisciplinary meetings and by email was not effective at all sites. Some sites had unique challenges, which only came to light after face-to-face meetings with individual staff. While time consuming, having local meetings at multiple sites was found to be a more effective way of addressing persistent problems. We underestimated the length of time it might take for staff to adopt the new practices, while staff groups agreed on the benefits of introducing the checklist it took longer than anticipated for this to be reflected in a sustained change to practice. If a similar project was undertaken again, we would make more use of local champions to engage staff at different sites.

### CONCLUSION

The project achieved the aim of reducing IUC never events to zero within 6 weeks. We believe the main intervention that led to the improvement was the introduction of a checklist prior to insertion of IUC which was, over time, successfully embedded into routine practice.

There is currently no national guidance on processes to ensure safe IUC insertions. However, since IUC events have been added to the never event list, the Faculty of

Sexual and Reproductive Health has been working to produce national guidance for safety standards for IUC insertion. In the interim, CNWL introduced local changes to IUC policy including changes to the IUC storage and the use of QI methodology to design, implement and monitor the use of an IUC checklist, similar to the WHO surgical checklist, to standardise the process of confirming the correct IUC device during insertion.

These changes have now been in use for over 30 months within all CNWL sites, no IUC never events have occurred since their introduction, spot checks confirm their use is sustainable. The changes were cost neutral but have had significant benefits in reducing risk and thereby enhancing patient safety and experience

**Contributors** JP: primary author responsible for project design, data collection and write up. SE: initial concept and overseeing the project. EJ: contributed to concept, data collection and write up. AR: pharmaceutical advice. TB: contributed to project design and write up.

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