

# BMJ Open Quality **Doing today's work today: real-time data recording and rolling audit in an IVF clinic**

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## ABSTRACT

The assisted conception unit at Sheffield Teaching Hospital NHS Foundation Trust provides in vitro fertilisation treatment. A team of seven embryologists provides a routine clinical laboratory service, involving culture and storage of embryos. This requires a series of management and statutory data administration and communication tasks.

We were aware that these were often done many days after clinical tasks, resulting in delays sending patient correspondence and unavailability of clinical notes for multidisciplinary team (MDT) cycle-review meetings. Embryologists also complained that transcribing data were time-consuming and duplicated across our *IDEAS* software, spreadsheets and paper.

We process-mapped our processes and gathered staff views on problems and potential solutions. The baseline average total cycle time (TCT) for completion of all administrative steps was around 17 days; data administration time (DAT, data 'touch time') was around 30 min per patient.

We embarked on this Quality Improvement (QI) project to reduce waste in TCT and DAT, and to have data available for patient communication and MDT deadlines. Exploration of *IDEAS*' capabilities led to progressive realisation of how much could be transferred to this single data system, removing a lot of off-putting redundancy. Through this we developed a 'to-be' vision of all data entry being real time, as part of the clinical 'jobs'. We conducted five Plan-Do-Study-Act cycles plus two more to test performance and sustainability as changes bedded-in and an external constraint disappeared.

We have cut TCT to 0 or 1 days and DAT to around 18 min. All project metrics are reliably within our targets, and data are now always available for timely patient letters and the MDT. Other benefits include easy access for all staff to patient records and removal of paper and spreadsheets. A further, unanticipated, benefit was a switch from a tedious 2 yearly storage tank audit to a more-agreeable and safer rolling audit.

## PROBLEM

Administrative processes within assisted conception unit (ACU) have evolved over the last few decades, often resulting from workarounds following incidents or regulatory changes. This is common in the UK National Health Service (NHS), making QI harder.<sup>1 2</sup> Although we had made

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Laboratory-based services in hospitals often suffer from inefficient routine administrative processes, including poor use of available Information Technology (IT) systems, which can have negative impact on clinical processes and staff workloads.

## WHAT THIS STUDY ADDS

⇒ This study demonstrates the dramatic impact that can be achieved by making fuller use of a core IT system and integrating administrative data-input tasks with the clinical activities that generates it.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This paper highlights that clinical scientists can, and should, take the initiative to streamline their routine administrative work, for the benefit of patients, clinicians and themselves.

improvements in recent years, such as switching from some paper-based data collection to spreadsheets, considerable scope to save staff time and provide a better service to patients and clinicians remained.

During in vitro fertilisation (IVF) cycles, the multidisciplinary team (MDT) and clinical embryologists capture and store much patient-level data for clinical decision-making, regulatory reporting and supporting evidence-based practice through research. This involved several electronic and paper systems, with duplication of entry. There was generally considerable delay in data entry, since staff saw this as relatively low priority, and many steps were the responsibility of particular individuals—so absence or part-time working stalled workflow, eventually completed in batches.

Our initial analysis revealed the extent of duplication and delay. Each patient IVF cycle (as laid out in [figure 1](#)) consumed ~30 min of data administration time (DAT) and the total cycle time (TCT) from embryo freezing to completion of administration was around 18 days. In contrast, patients generally have a pregnancy test and MDT review after ~9 days.



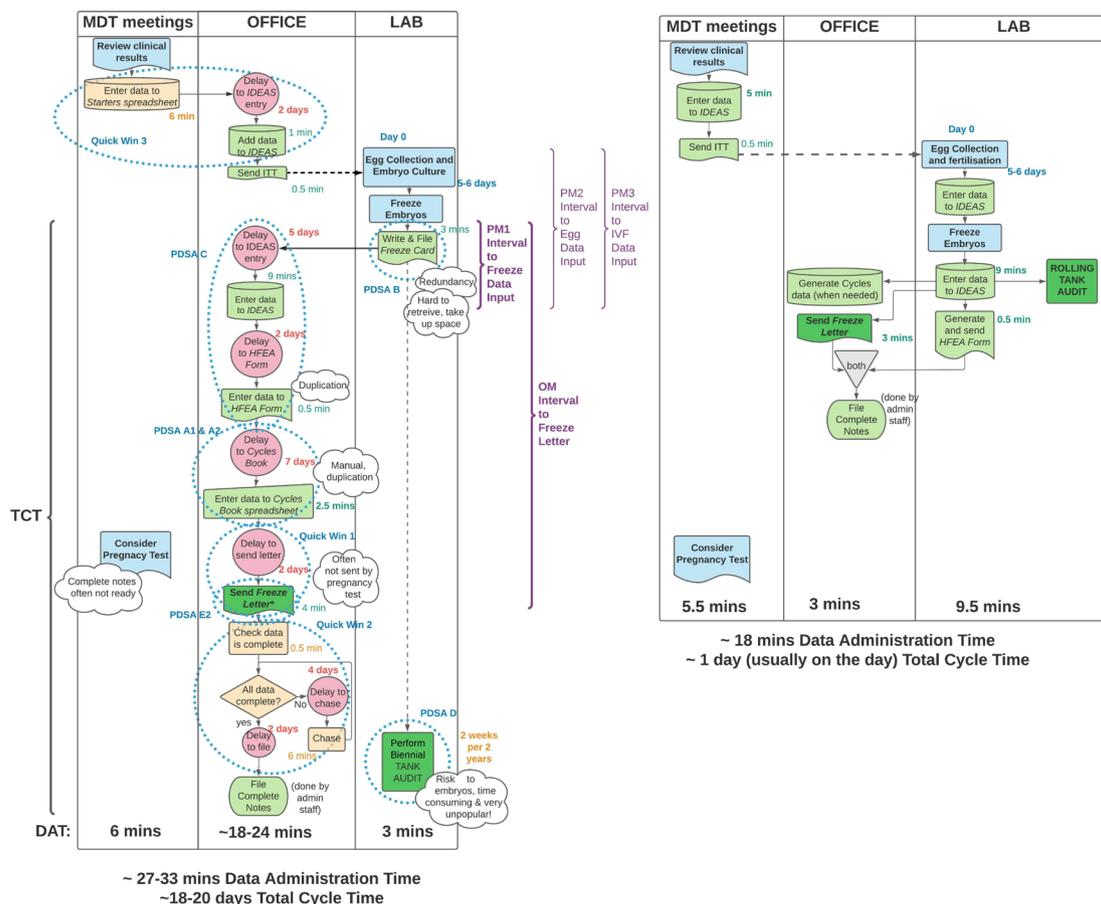
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**Figure 1** Process maps of administration involved in a patient IVF cycle at ACU. Left: As-Was (original) Condition Right: As-Is (current) Condition red=unnecessary waste, Orange=necessary waste, Green=value adding steps. We’ve distinguished between a darker green representing value from the point of view of the patient and clinicians involved in the cycle, and a lighter green which are or were clear value to ACU to ‘do the job’ or comply with regulation. Blue are clinical activities important to time anchors. \*Some expediting when long delays were noticed. (PDSA E1 Is not shown—it was a ‘go-and-see’, without a predesigned change intervention), interval between embryo freezing and generating the Freeze Letter for the patient (days) PM1 = Process Metric 1: interval between embryo freezing and inputting the freeze data to IDEAS (days) PM2 = Process Metric 2: interval between day 0 and inputting the egg data to IDEAS (days) PM3 = Process Metric 3: interval between day 0 and completing entry of all the IVF insemination data to IDEAS (days). ACU, assisted conception unit; ‘day 0’, egg collection from the patient; DAT, data administration time; IDEAS, IVF database software system; ITT, intention to treat; IVF, in vitro fertilisation; MDT, multidisciplinary team; OM, outcome metric; PDSA, Plan–Do–Study–Act; TCT, total cycle time.

Consequently, information was often not readily available to patients when it would reassure them and when required by the MDT.

There is evidence that stress during IVF impacts outcomes, both the chances of pregnancy in an IVF cycle and of persevering through the optimal number of cycles.<sup>3–6</sup> Clinic staff are, of course, fundamental to patient experience, with one driver being the coordination and administration of treatment,<sup>3,7</sup> though the importance of this is not always so apparent to staff themselves.<sup>8</sup> Data not being available for the MDT reviews meant staff (including consultants) wasted time while data were searched for across the various data systems and locations throughout the process. Our poor process therefore had clinical and experiential impact on both patients and staff.

With no external targets for administrative processes, our aim was to remove waste, saving staff time and

providing a better service. In ACU, we use IDEAS, the commercially supplied electronic database software specifically designed for IVF services.<sup>9</sup> Our initial change idea was to use IDEAS to replace a spreadsheet system, where we noted particular data-entry redundancy and delay. (This spreadsheet is known as the ‘Cycles Book’, which we were using to aggregate the data necessary for research purposes and for generating laboratory-level clinical metrics including pregnancy rates.) We had tried to make this spreadsheet redundant previously, but had been unsuccessful.

While working on testing this change, we progressively investigated further IDEAS functionality, and so generated, tested, refined and implemented further change ideas. In addition to removing steps that were wasting staff time (non-value-adding) and delaying data availability for patients and clinicians, these ideas addressed data quality and risk to frozen embryos (an organisational

risk): ‘hidden’ problems. Thus, we ended up tackling problems for three sets of stakeholders (patient and MDT ‘customers’, staff and the Trust)—it became a ‘Three Wins’ project.<sup>10</sup> We were guided by our trust’s QI approach: clinical microsystems.<sup>11–13</sup>

## BACKGROUND

IVF cycles involve sensitive and highly-regulated tasks.<sup>14</sup> Figure 1 shows process maps for this project. We start by describing the general process.

The intention-to-treat (ITT) decision is made and shared at an MDT, based on clinical data. ITT must be reported to the UK Human Fertilisation and Embryology Authority (HFEA). Embryology procedures begin when the patient attends our clinic for Egg Collection (which we refer to as ‘day 0’). This is followed by fertilisation with sperm in the lab (the IVF itself), fertilisation check, embryo culture, plus transfer and/or freezing (on day 5 or 6). Data associated with these tasks are documented by hand on a paper Labsheet, including careful recording of embryo location. As above, aggregate data from IVF cycles are also required for research purposes and for calculating overall pregnancy rates, etc.

The patient is notified about the number of embryos frozen via letter, known to us a ‘Freeze Letter’. Ideally, for reassurance, a patient would receive their Freeze Letter immediately after the embryo freezing. Typically, the MDT meets around 9 days after freezing to review pregnancy test results; they should have access to complete data. Labsheets are inspected for completeness then filed in the clinical notes.

A further regulatory requirement for an embryology team is to audit the contents of the cryostore tanks (where the frozen embryos are stored), at minimum every 24 months, typically taking 2 weeks of an embryologist’s time. This exposes embryos to risk of thawing<sup>15</sup> and is an unpopular task with staff.

As common in many NHS labs, administration was seen as a secondary, tedious task, with many paper and ad hoc spreadsheet systems: a convoluted maze of paperwork and forms (eg, online supplemental files S3–S5) that is confusing for new staff. Though we have a core IT system (IDEAS), this was updated with IVF cycle data retrospectively and only from computers in the office.

Changing ingrained ways of working and establishing new habits is hard.<sup>16 17</sup> There was little overt QI culture in ACU: implicit regarding clinical processes, but not administration. We anticipated the main challenge would be encouraging the behavioural change of incorporating administrative data capture as part of ‘real time’ work rather than separate tasks which could be postponed.

The clinical microsystems approach was designed to help clinical teams redesign their services and was systematised at Dartmouth in the USA.<sup>11–13</sup> Our trust hosts the UK’s first Microsystem Coaching Academy (MCA).<sup>18 19</sup> We used MCA material, but did not have MCA training or facilitation.

Here, the clinical microsystem is the embryology laboratory team’s administrative system, which feeds into the macrosystem of the wider Trust fertility service. An MCA template guided the overall QI project and phases of testing successive change ideas. An example for our Change Idea C (‘Add all lab data to IDEAS in real time’—see the Design section) is shown in online supplemental file S1. This template supports the thinking to guide Plan–Do–Study–Act (PDSA) experiments, similar to the three questions of the Model for Improvement,<sup>20</sup> more commonly used in the NHS, including in recent in clinical sciences QI projects.<sup>2 17 21 22</sup>

Our work fits the definition of QI as ‘fundamentally a process of change in human behaviour ... driven largely by experiential learning’.<sup>23</sup> Success here would mean not just improved performance in the process, but a shift in ACU culture to an appetite for further QI.

## MEASUREMENT

We assessed current issues through two methods: process waste mapping and a 4N Chart.<sup>24</sup>

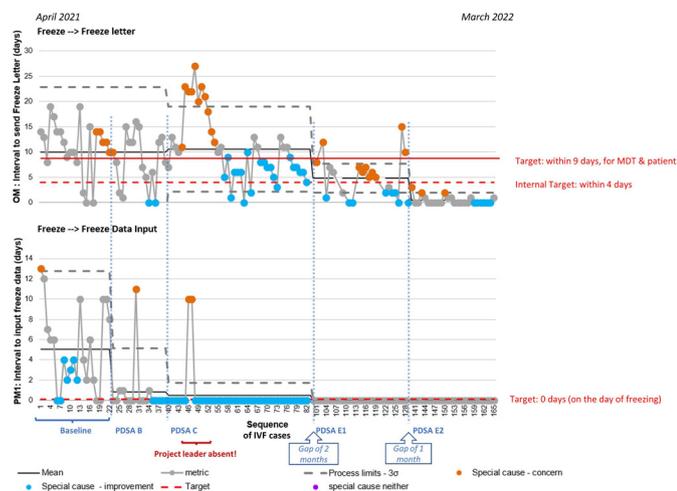
The initial (‘as-was’) process map is shown in figure 1 (left). As noted earlier, this QI project evolved as we realised the potential for greater use of the IDEAS software, prompting us to target further areas of waste and develop a more ambitious vision for a ‘future state’ (figure 1, right). Within the overall aims, iterative decisions on specific aims for component phases is a feature of a worthwhile QI project.<sup>25</sup> Thus our metrics and focus evolved over our project, rather than being designed from the outset.

Steps are colour-coded as ‘pure’ waste (red), (currently) ‘necessary’ waste (orange) and value-adding (green)—dark green for value to the patient or clinician, a lighter green for value to ACU to ‘do the job’ or comply with regulation. These light-green steps are also targets for improvement. Blue steps are clinical, included as important time anchors.

As figure 1 (left) shows, the process was fragmented, with particular members of staff assigned to each of the office data processing tasks, conducted retrospectively and with many duplicate data-entry steps and storage media. We show estimates for the durations (minutes) of each step and the delays between (days).

We had two overall aims: reducing TCT and reducing DAT. However, these were hard to measure with the accuracy and frequency we wanted: workflow was not always linear (as portrayed), with occasional expediting of a case to avoid particular delays. There were few routine time-stamps in the data (including not recording the final Filing date). Figure 1 shows estimates from intensive snapshots of this complicated system.

For more regular measurement, we focused on recorded time-stamps, from which we could back-calculate intervals to analyse with statistical process control (SPC) charts<sup>26</sup> using the NHS ‘individuals’ template<sup>27</sup> (modified to display a larger number of datapoints and sequence



**Figure 2** Performance metrics: OM and PM1 (PM2 and PM3 are in online supplemental file 1). IVF, in vitro fertilisation; MDT, multidisciplinary team; OM, outcome metric; PDSA, Plan–Do–Study–Act.

number (successive IVF cases) on the X-axis rather than dates).

The interval between embryo freezing and generating their Freeze Letter matters to the patient, so we considered it an outcome metric (OM). The average interval was around 10 days (figure 2, OM, baseline); the process map shows typical delays to each step which are longer; the mean is reduced by the practice of expediting some Freeze Letters (as can be seen on the SPC). The ideal would be the patient routinely receiving their Freeze Letter as soon as possible after the Freeze event. Pregnancy testing and the MDT review generally occur around 9 days after embryo transfer and freezing, so we decided a reasonable target would be to send the Freeze Letter within 4 days of freezing. This allows for weekend working delays as they are typically generated Monday to Friday.

The usual prerequisite (really the only one) for sending the Freeze Letter is for the related data to have been inputted, so this was a process metric (PM1), with a baseline value (delay) of about 5 days (figure 2).

As noted, data entry from the paper Labsheet (used in the lab) was very fragmented. We added two more process metrics which we could calculate: PM2 is the delay to enter the egg collection data; PM3 is the delay to complete entry of all IVF insemination data. Both of these have egg collection (the ‘day 0’ patient attendance) as the clock-start time (see figure 1), this is typically 5–6 days before embryo freezing. Their SPC charts are shown in online supplemental file S6. Long delays (10 days on average) are evident. To be available in time for the MDT review, all data should be entered within 14 days; we set an internal target of 6 days.

The downward sawtooth slopes on some of the SPCs, in particular the OM (figure 2), are indicative of batching: for example, the Generate Freeze Letter task was (initially) being done only once per fortnight.

Other particular problems are noted on figure 1 (left) in the cloud symbols. Embryo location in the cryostore

tank was handwritten on a paper record (a ‘Freeze Card’—see online supplemental file S5 for examples). These cards were filed alphabetically which is time consuming. They were often misplaced or illegible and took up space within the cryostore. The cards were an example of duplicate data entry since the information on them could be retrieved from either IDEAS or the clinical notes. The 2-week long physical cryostore tank audit had to be scheduled into rosters every other year.

At the start of the project we also asked ACU colleagues (via email) to complete a 4N Chart. Collated results are shown in online supplemental file S2. They show our staff were dissatisfied with the inefficiencies of the administrative workload, confirming that improvement would be considered a worthwhile goal. We considered the 4N data alongside the process map to generate change ideas.

## DESIGN

The QI project was led and executed by the lead author (LW), working within her ‘circle of influence’ by focusing on embryology-based tasks.

We used Sheffield MCA’s QI template driving conventional PDSA cycles to test and refine each Change Idea. Improving TCT and DAT remained the main aims. Each PDSA cycle inspired new avenues of exploration of the process and how to extend use of IDEAS. Some of these were substantial change ideas, justifying PDSA testing, others were ‘Quick Wins’ (or ‘Just Do Its’)—changes agreed to be obvious and very unlikely to be problematic.

We gather the four Change Ideas and three Quick Wins together here, in the order in which they were tested and implemented, to aid clarity.

The motivating idea for the project was to remove waste in the administrative tasks through making better use of our existing IDEAS software. Conversations with and experiences at two other IVF units also using IDEAS provided insight and encouragement to make the changes to our own system. The lead author (LW) explored the functionality of IDEAS via in-house training, online demos and instructions from the software vendor.

### Change idea A: automate the creation of the cycles data

**Aim:** eliminate the waste step ‘Enter Data into Cycles Book Spreadsheet’ and the preceding delay (see figure 1 left vs right). This was duplication and a tedious (and error-prone) manual task. This spreadsheet was cumbersome, with potential version control and backup risks.

The preceding delay (typically 7 days) was the (paper) Labsheets sitting in the Cycles Book tray (online supplemental file S4A) awaiting the ‘Enter Data’ step. The majority of these data are already on IDEAS. This might be extracted automatically, and saved to an Excel file in a similar layout to the old Cycles Book whenever needed, through running an IDEAS query script. Our previous attempts to create an IDEAS query had been unsuccessful due to lack of time dedicated to learning its full potential and lack of training on the software. Testing this change

could be undertaken by one individual without disruption to the regular service, so we considered this the best place to start PDSA trials. Success would mean we could archive and retire the Cycles Book spreadsheet.

#### Change idea B: use IDEAS for cryostore location data

Through increased exposure to IDEAS through Idea A, we realised how useful the software could be. This inspired further ideas for streamlining our protocols, including to access IDEAS in the lab instead of writing paper Freeze Cards to keep in the cryostore. As noted, the Freeze Cards (online supplemental file S5) were problematic: time consuming to file and retrieve, error prone and occupying cryostore space. Success would mean we could archive and retire Freeze Cards.

#### Change idea C: add all lab data to IDEAS in real time

Following the success of Idea B, we decided that all lab-procedure data should be entered into IDEAS in real time (ie, as soon as the lab work is completed). Required data for the HFEA Form and the Freeze Letter would be available from this point.

#### Change idea D: switch to a 'rolling' cryostore storage tank audit

Idea B involved using IDEAS instead of paper Freeze Cards. We then realised it might also allow replacement of the biennial tank audit with a 'rolling' audit conducted when removing embryos for treatment or disposal. This procedure is supported in literature.<sup>15</sup> Success would mean removing from staff workload the 2-week long audit of 100 random patients and reduce the consequent thawing risk to frozen embryos (online supplemental file S7).

#### Quick win 1: generate automatically populated Freeze Letter

With increased exposure to IDEAS functionality, we discovered a reports feature to extract data and populate a letter. Since all required data were now being entered in real time, we realised that we could quickly generate a Freeze Letter for the patient as soon as lab work was completed.

#### Quick win 2: checking data completeness in real time

This had also been a source of delay and staff time waste. A simple change in protocol to make staff entering data responsible for checking in real time (rather than leaving it for retrospective chasing) would eradicate this administrative step and its delay.

#### Quick win 3: enter data from MDT tasks in real time

Instead of postponing administrative tasks arising from the initial MDT meeting (often for several days) these could be completed in real time by accessing IDEAS on a laptop in the meeting, removing a waste step and another spreadsheet.

Together these ideas gave a vision of an ideal 'to-be' process, shown in [figure 1](#) (right).

## STRATEGY

We used the MCA improvement template to initiate the project, focusing initially on eliminating the particularly cumbersome Cycles Book spreadsheet and step. We then had further change ideas, leading to multiple PDSA cycles, as guided by the template.<sup>19</sup> We targeted most tasks on the process map, with the aim of reducing TCT, DAT or both.

Over the course of this QI project, we tested and refined our four change ideas over seven cycles of PDSA and also implemented three Quick Wins, summarised in [table 1](#).

#### Change idea A: automate the creation of the cycles data

We conducted two rounds of PDSA, A1 and A2, with training on IDEAS and refining the data extraction script. With a set of test cases we found we could capture the required Cycles data from existing IDEAS content (50 of the previous 53 variables, with the other 3 judged unnecessary) and automatically generate a suitable Excel spreadsheet on demand. We found these data had been entered to IDEAS reliably. We looked at test cases, so did not impact live performance. With success in A2 we removed the old Cycles Book spreadsheet processing (considerably reducing the burden on one staff member) and its postponement delay.

#### Change idea B: use IDEAS for cryostore location data

In PDSA B, we trialled a protocol for live input of freeze data in the lab. Precise embryo location is a critical (and regulatory) issue, so the reliability of the IDEAS-only data had to be monitored carefully during testing.

Auditing data accuracy showed this could be much more accurate than the paper system: an audit found that 85% of data errors arose from the Freeze Cards and that these could be eliminated by witnessing data entry to IDEAS. The impact of improvement to this early-stage of the flow is evident on the SPC for Freeze Data Input interval (PM1, [figure 2](#)): PM1 is reduced from 5 days to usually 0. On three occasions PM1 lapsed to around 10 days due to lone working on a Sunday. Without reassurance, the embryologist was hesitant to use the new protocol. We see the change also improved Egg Data Input (PM2, online supplemental file S6) since staff must enter the egg collection data at this point too. The change was successful and retained.

As expected we did not yet see an improvement in the OM—downstream admin delays were still very substantial.

#### Change idea C: add all lab data to IDEAS in real time

The successful expansion in IDEAS use prompted us to try capturing the rest of the IVF data. We notice staff had already started using IDEAS for real time (day 0) entry of egg collection data (PM2, online supplemental file S6). The IVF data (PM3, online supplemental file S6) shows the impact.

We did not get the impact we had hoped for on the Freeze Letters ([figure 2](#), OM). We can observe a particularly problematic period around case 46—particularly

**Table 1** Improvement cycles

PDSA cycle	Plan/prediction	Do	Study	Act/conclusions
A1	Programme <i>IDEAS</i> to automatically generate Cycles data (53 variables required). <u>Prediction</u> Can be achieved (this time!). Will decrease TCT and DAT.	Train on <i>IDEAS</i> functionality (30 min) Design template to extract relevant variables (3 hours) Test on previous year's data (2020)	49 of 53 variables were extracted. Found that data in <i>IDEAS</i> had been entered reliably. DAT could be reduced by ~2 min TCT will be unchanged	Worthwhile improvement and proof of principle. Needs refinement for remaining 4 of the 53 variables.
A2	Troubleshoot and refine automated Cycles data extraction <u>Prediction</u> <i>Cycles Book Spreadsheet</i> can be retired. Will decrease TCT and DAT.	Discuss relevance of omitted variables. Refine programming to extract omitted variables (3 hours) Test on previous year's data (2020)	Agreed three variables unnecessary. Extraction of 50/50 variables successfully automated. DAT will be reduced by 2.5 min TCT will be reduced by 7 days	Archive and retire the Cycles Book Spreadsheet – from now on generate a data worksheet on demand. <i>IDEAS</i> has further functionality worth exploring.
B	Use <i>IDEAS</i> to hold embryo location data (added in real time) <u>Prediction</u> Paper <i>Freeze Cards</i> can be retired	Amend standard operating protocols: Embryologist to add storage details onto <i>IDEAS</i> in real time in lab. Arrange lab meetings (many, online) to train staff and gather feedback. Run new and old systems in parallel during trial. Audit data entry errors.	OM not yet improved (10 days): downstream delays PM1 reduced from 5 to 1 days PM2 reduced from 10 to 4 days <u>Retrospective audit error cause:</u> Paper system: 85% <i>IDEAS</i> system: 15% All errors were resolved. Double witnessing system reduced errors to 0%. DAT slightly reduced, TCT unchanged	Clear benefits using new system → transcribe data from all current freeze cards onto <i>IDEAS</i> . Archive & retire paper <i>Freeze Cards</i> → use <i>IDEAS</i> data from now on. Continue audit to monitor data accuracy. Need to tackle more data entry delays to shift OM and TCT: <i>Labsheets</i> still waiting in multiple trays.
C	Use <i>IDEAS</i> to store all remaining lab process data (added in real time in the lab). <u>Prediction</u> Will take time for Embryologists to adjust: data input will be hit and miss - but will then further reduce TCT and DAT.	Give embryologists a demo, and send instructions to all (email). Post reminder sign at lab exit: 'Have you put your procedures on <i>IDEAS</i> ?'	OM not reduced (10 days): problem when project leader absent; when returned reduced to 7 days. PM2 reduced from 4 to 1 days PM3 reduced from 11 to 4 days DAT reduced by ~10 min to ~18 min	Have now removed manual systems. Learning: Entry of IVF data to <i>IDEAS</i> (PM3) by Day six is adequate Important to have wider responsibility for stages. Investigate potential to switch from biennial to a rolling audit of storage tanks in cryostore.
D	Use continuing data audit to do the job of the biennial cryostore audit <u>Predictions</u> Can replace biennial audit (so reducing workload and risk of embryo thawing).	Conduct audit and a risk assessment to gauge the safety of switching to a rolling audit model	Rolling audit is satisfactory. Risk score reduced from 6 to 3 for accidental embryo thawing.	Cease biennial audit (removing two person-weeks of workload per 2 years and reducing risk): considered a major win!

Continued

**Table 1** Continued

PDSA cycle	Plan/prediction	Do	Study	Act/conclusions
E1	Test to check system performance and whether sustained <u>Prediction</u> New protocols working, but delays expected (pending HFEA Form web interface)	Resume collecting and calculating all interval metrics	OM reduced from 10 to 5 days, delays due to interface as expected. Freeze data (PM1) 100% 0 delay, but delays evident downstream. <i>Surprise!:</i> Some gaps in OM data: 8 Freeze Letters had been missed: a flaw discovered in the system. TCT reduced to around 5 days	Fix freeze letter flaw and monitor. Recheck system performance when HFEA Forms interface running.
E2	HFEA Form available: retest system performance check system performance and sustained levels <u>Prediction</u> System now has no external constraints, will be working close to optimal.	Resume collecting and calculating all interval metrics	All metrics have control limits within targets: statistically reliable. TCT reduced to 0 or 1 day. Project aims met. Getting close to vision of all admin data entry on the day of clinical activities.	A great success. Worthwhile to share our revised and safer processes with other IVF units. Continue with QI: consider what to address next.

DAT, data administration time; HFEA, Human Fertilisation and Embryology Authority; IVF, in vitro fertilisation; OM, outcome metric; PDSA, Plan–Do–Study–Act; TCT, total cycle time.

impacting this stage. This was the result of the project lead being absent. It reinforced the need to change from individual to team responsibility for progressing all stages. Some batching of work is also still present, indicated by the sawtooth patterns.

#### Change idea D: switch to a ‘rolling’ cryostore storage tank audit

We trialled continuous ‘rolling’ audit of data accuracy to test the feasibility and impact of this change, finding it satisfactory and to lower risk to embryos from thawing during unnecessary removal from the tank. It does not impact our metrics directly, but will release capacity over the medium term.

#### Quick win 1: generate automatically populated Freeze Letter

We found this worked: Freeze Letters could be generated in an instant, and by more members of staff. (Of course, they still require proofing, printing and posting.)

#### Quick win 2: check data completeness on entry

A simple change in protocol to make staff responsible for data completeness in real time successfully eradicated another administrative task. As [figure 1](#) suggests, this saves around 2–4 days in TCT and cuts DAT by ~6 min.

#### Quick win 3: enter data from MDT tasks in real time

Taking IDEAS on a laptop to the initial MDT meeting enabled real time data entry, removing the intermediary

Starters spreadsheet and the later transfer of data from it to IDEAS.

#### Check sustained performance

The project concluded with ‘go and see’ PDSAs (E1 and E2), resuming calculation and analysis of metrics to test for sustained improvement. In E1, the wait for the new HFEA Form national web submission interface caused delays, as expected, but a surprise was discovering that some Freeze Letters were not being sent. We fixed this glitch and set up a system alert when data were ready for the Freeze Letter, monitoring for completeness. When the web submission interface was operational (so there were no further known constraints to the system working as intended, [figure 1](#), right), we conducted E2.

#### RESULTS

The SPCs ([figure 2](#) and online supplemental file S6) show we are now reliably within our target performance levels on all four metrics (the upper control limits (grey dashed lines) are lower than the targets (red lines)). In particular, we send a patient their Freeze Letter (OM) before their pregnancy test, and all IVF data are on IDEAS for the MDT review meeting, so we have met our ‘customer service’ aims.

Beyond that, we have come a long way towards the zero-delay, on-the-day working we aspire to ([figure 1](#), right). The final round of sustainability testing (E2) shows:



- ▶ The Freeze Letter was sent on the day of embryo freezing (our output metric, OM) on 18 of 26 occasions (70%, mean delay 0.5 days vs 10 before the project).
- ▶ Freeze data were input on the day of freezing (PM1) on 26 occasions (100%, so zero delay vs 5 days initially).
- ▶ Egg data were input on day 0 (PM2) on 21 occasions (81%, mean delay 0.5 days vs 10 initially).
- ▶ All IVF data were on *IDEAS* on day 0 (PM3) on 15 occasions (58%, mean delay 1 day vs 11 initially).

We have removed two spreadsheets, the paper Freeze Cards and duplicate data entry from many steps. Removing the biennial cryostore audit is also a major win, reducing risk to embryos, releasing staff time and removing a ‘niggle’.

We estimate that we are spending around 10 min less on DAT per patient IVF cycle, and the TCT (after embryo freeze) is down from around 18 days to 0 or 1 day: we have moved almost completely to real-time data entry to *IDEAS*. Data entry is now less painful and more-clearly ‘part of the job’. The 2-day delay after the initial MDT (earlier than our metrics start) is also gone.

## LESSONS AND LIMITATIONS

The global pandemic led to significant changes in working practices in ACU, including more workaround paper-based checks prior to starting treatment. Adapting and settling to a ‘new normal’ was a strain on all staff. *QI* added additional pressures, hence we decided to start with small improvements within the embryology team only. It takes time to understand new protocols and change practices. We learnt the importance of improving in stages, avoiding overwhelming staff, and gauging the impact of each change. We overcame reluctance to change through regular team meetings and one-to-one explanations and support.

It took time to explore and exploit the potential of existing software (*IDEAS*), and it was worthwhile discussing this with other users. Spreading knowledge and confidence in software across a department also takes time and patience. But all this was richly rewarded.

As the results show, we have made the major cultural shift to data entry on the day of the clinical activity. An exception sometimes is the IVF insemination data (PM3). Though this is lower priority and not delaying information for patients and MDT, it has the potential to be missed until it does impact; we still hope to achieve this completeness to culture change, though acknowledge that staff have been through a lot of change and systems pressure.

Though we achieved some dramatic results, there are of course limitations. In particular, we struggled with metrics, partly as the scope of the project kept widening as further change opportunities became evident. This was compounded by the fragmented process, occasional expediting of IVF cases and by lack of recording of some useful data. For example, we lacked time-stamps for the

end of each IVF process cycle. In retrospect, we might have recorded them manually from the start for a baseline and then throughout. We might also have looked more directly at the impact on ‘customers’: recording the availability (or otherwise) of types of data at each MDT meeting (we will do this in future as part of monitoring ongoing performance), and might have sought patient feedback on their experience of being kept informed. We were able to back-calculate durations for most delays, but had to estimate other steps by staff noting times during limited ‘snapshots’. More discipline with a *QI* framework and cause-effect-structuring tools<sup>28</sup> early on may have driven more systematic development of a wider and more-detailed hierarchy of metrics.

Events external to the project (holiday leave, national-reporting IT changes) caused some disruption, sometimes making impact less immediate and obvious than we had hoped. Further, we note that the change in mindset about data recording and the familiarity of routine *QI* thinking is an ongoing process of reinforcement and habituation.

## CONCLUSION

This project has been very successful. ACU had a practice of specific staff entering (often duplicating) data onto spreadsheets and paper, with long delays in between—which often impacted on patients and MDT decision-making. Now we have a streamlined, delay-free, integrated system that can be accessed and used by all staff and the MDT. Though *IDEAS* software had been available to ACU for many years, this *QI* project pushed us to understand and exploit its fuller functionality. Future improvements could include wider MDT use of *IDEAS*, becoming feasible as the culture shifts. This project represents the beginning of a new era of ACU electronic data management. We are keen to disseminate these changes, including specific improvements like the rolling cryostore audit.

The project has also helped develop a culture of teamwork and continuous improvement of clinical administration. It became apparent through the project that assigning tasks to a particular embryologist made workflow inefficient and fragile. We are moving towards all staff understanding the whole system, which is also very valuable for cross-fertilising improvement ideas.

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