Quality assessment of donor liver procurement surgery using an unadjusted CUSUM prediction model: a practical nationwide evaluation

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ORIGINAL ARTICLE

Quality assessment of donor liver procurement surgery using an unadjusted CUSUM prediction model. A practical nationwide evaluation

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Abstract

Background: The aim of this study was to analyze the value of the unadjusted CUSUM graph of liver surgical injury and discard rates in organ procurement in the Netherlands.

Methods: Unadjusted CUSUM graphs were plotted for surgical injury (C event) and discard rate (C2 event) from procured livers accepted for transplantation for each local procurement team compared with the total national cohort. The average incidence for each outcome was used as benchmark based on procurement quality forms (Sep 2010–Oct 2018). The data from the five Dutch procuring teams were blind-coded.

Results: The C and C2 event rate were 17% and 1.9%, respectively ($n = 1265$). A total of 12 CUSUM charts were plotted for the national cohort and the five local teams. National CUSUM charts showed an overlapping "alarm signal." This overlapping signal for both C and C2, albeit a different time period, was only found in one local team. The other CUSUM alarm signal went off for two separate local teams, but only for C events or C2 events respectively, and at different points in time. The other remaining CUSUM charts showed no alarm signaling.

Conclusion: The unadjusted CUSUM chart is a simple and effective monitoring tool in following performance quality of organ procurement for liver transplantation. Both national and local recorded CUSUMs are useful to see the implication of national and local effects on organ procurement injury. Both procurement injury and organ discard are equally important in this analysis and need to be separately CUSUM charted.

KEYWORDS
liver transplantation, organ procurement

1 | INTRODUCTION

Professional training and certification of abdominal organ procurement for transplantation was implemented in 2010 as a national curriculum, mandatory for the five local procurement teams in the Netherlands. The intention was to optimize the surgical technique in order to improve the quality of abdominal organ procurement and to increase organ yield.[1] In short, trainees have to attend a 2 day hands-on masterclass, pass an e-learning multi-visceral procurement module, and keep a logbook of minimal 10 successful procurements under supervision before being allowed to be examined by an independent procurement surgeon during a live unsupervised case. After passing this final exam, they become certified as independent procurement surgeons. A national board, known as the "Landelijk Overleg Regionale Uitname Teams" (LORUT), composed of an expert panel from each of the five local teams, was installed to oversee this surgical training and certification. Its other tasks include harmonizing standard operative procedures between the local procurement teams, supporting organ donation in donor hospitals, regulating logistical challenges, maintaining liaison with partners in the field of the individual organ transplantation boards, and facilitating research initiatives in procurement surgery with the aim of improving quality and innovation (Table S1).

Monitoring at present is done by analyzing electronically submitted organ quality forms for reported disparities between the findings of the procurement and transplant surgeon respectively and whether organs were surgically damaged. These findings have been categorized and analyzed previously with the intention to improve clinical practice.[2] This standardized way of data acquisition across multiple programs with regulated retrospective auditing has allowed further quality improvement in the transplantation field worldwide. Nevertheless, this type of auditing comes with a time delay before corrective changes due to the retrospective nature of data collection.[3] In order to minimise this delay, cumulative sum (CUSUM) analysis plots have gained popularity in the field of transplantation as a nationwide real-time monitoring tool.[4–7] CUSUM analysis plotting is based on sequential monitoring of cumulative performance in real-time and was first described in industrial manufacturing.[8] The CUSUM curve rises whenever an unwanted event occurs and falls or flattens whenever a favorable outcome is achieved or maintained, respectively. When performance worsened, one expects to see an increasing curve while a flat curve is seen in uneventful performance. The level of the curve is compared against a pre-defined threshold or control limit (CL) which signals a change from the normally accepted outcome and is usually an alarm signal. It is ideally used in surgical outcome monitoring if the procedure is standardized, such as is the case in multi-visceral abdominal procurement surgery. Applying real-time monitoring could potentially limit the loss of vital organs due to early alerting of surgical teams that they need to improve their outcome. This, in turn, would ultimately result in more patients transplanted because fewer organs would be discarded/lost after timely correcting the negative outcome.

The aim of this study was to analyze retrospectively the surgical injury rate of liver procurement and the resultant organ discard rate for transplantation using an unadjusted CUSUM chart model plotted for the Netherlands compared to the local independent organ procurement teams, as a simple executable analytic tool.

2 | METHODS

The research protocol was approved by the hospital ethical review as well as by the LORUT board. Time of procurement, local team that performed the procurement blinded with codes (I, II, III, IV, and V), quality forms on liver retrievals, and whether the liver was transplanted were collected from the Dutch Transplant Foundation database from September 2010 until October 2018. Missing and incomplete quality forms, livers that were retrieved without initially being offered for transplantation were excluded for analysis. A previously described scoring system was used to analyze the quality forms of both procurement and transplant surgeon.[2] In case of discrepancies in both quality forms the transplant surgeon's form was giving priority. Briefly, the scoring system labels procured livers evaluation in five distinct alphabetical categories based on the surgical findings; that is, A: no abnormality found on the liver, B: anatomy discrepancy between procurement and transplantation surgeon respectively, C: Iatrogenic surgical injury, D: non-surgical abnormality (e.g., steatosis) and E: other remarks (e.g., packaging). The scoring system also further subdivides the category C and D into transplanted (C1 or D1) or discarded (C2 or D2).[2] Only C and C2 categories were used as outcome variables for this study and corresponded to the injured liver and discarded due to this injury, respectively. These two distinct outcome parameters were independently used to plot unadjusted CUSUM charts for the whole cohort (national) and separately for each individual procurement team (local).

2.1 | Statistical analysis for unadjusted CUSUM chart

CUSUM were plotted according the established described statistical methods.[9] In order to determine how much the CUSUM charts would change, the incidence of an event (C or C2 event) needed first to be determined. This probability of taking place is in fact the average incidence rate for C and C2 events respectively (p(0)) when the procedure is as expected. The p(0) is then used to calculate the incidence rate at which performance would be considered suboptimal and not as expected (p(A)). For statistical purposes this value (p(A)) was set to be equal to twice the value of the expected rate (p(A) = 2p(0)) for C and C2 events, respectively. Only when both the p(0) and p(A) value have been determined, then the amount the slope would increase in case of an event or decrease when no events took place can be calculated. In case of an event, the slope would increase by $\ln(pA/p0)$), and in case no such event took place the slope would decrease by $\ln((1\text{-}p0) / (1 - pA))$. This would be started from the very first case in our analysis until the last case over time to achieve a CUSUM plot for the respective C or C2 events. This process was done for the total cohort (national) and the five local teams which would result in 12 separate CUSUM charts in

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TABLE 1 Simulated ARL (case number) for p0 and pA for C outcomes in liver procurement for a range of candidate CLs.

Candidate control limit (CL)	2	2.5	3	3.5	4	4.5	5
ARL in control (p = p0)	170	320	565	1005	1740	2935	4940
ARL out of control (p = pA)	30	40	55	65	75	85	95

TABLE 2 Simulated ARL (case number) for p0 and pA for C2 outcome in liver procurement, for a range of candidate CLs.

Candidate control limit (CL)	1	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
ARL in control (p = p0)	210	240	285	350	460	515	585	670	765	900	1040
ARL out of control (p = pA)	75	80	90	100	120	125	135	145	160	170	180

total. The p(0) and p(A) derived from the total cohort were all set at the same values for all CUSUM charts. The CUSUM is restricted so that it can never go below zero, this prevents a build-up of "credits" that could lead to a delay in the detection of problems.[9]

Once the CUSUM for C and C2 was plotted for the whole cohort, the CL or alarm threshold for the CUSUM was chosen. This choice is based on a statistical simulation which would give a true and false alarms. A specific number of cases is needed to get to that point in an artificial setting for a given CL. This specific case load number is known as average run length (ARL) in CUSUM terminology.[9] Therefore each CL value has a corresponding ARL for a true and false alarm (Tables 1 and 2). A lower CL will translate into a shorter ARL and thus a faster alarm signaling. The CL value is based on simulated ARLs for the true and false alarm taking into account the average number of cases per year. With an average of 250 cases per year for the Netherlands, divided over 5 local teams, this would give an average of 50 cases per team. From this, an estimate on the time needed until a true and false alarm gets off for C- (Table 1) and C2 events (Table 2). This subjective choice is a trade-off between avoiding too many false alarms (i.e., the horizontal line is too low and thus the case numbers [ARL] or time needed would be lower) and the missing of a true positive alarm or a false negative when there should be an alarm (i.e., the higher case number [ARL] or longer time needed before the alarm goes off). For all local teams, one common CL was chosen which is lower than the national CUSUM because of the lower average number of cases annually. A more in-depth explanation is included in the supplement (Statistical supplement for CL calculation).[9]

3 | RESULTS

Since digital registration was initiated from May 2011, only a total of 1897 procured livers with digital completed quality forms (May 2011–Oct 2018) were available to evaluate. The basic donor demographics and surgical procedures information are shown in Table 3. After only considering livers that were initially offered for transplantation before procurement and excluding 13 missing or incomplete quality forms, 1265 procurements remained to be analyzed. Of those, 215 (17%) were injured during procurement (C event). From those injured, 24 were irreparably damaged (C2 event) and discarded (1.9% of the 1265 analyzed procedures) for liver transplantation. Thirteen of these livers were refused after procurement because of irreparable vascular injury (1% of the 1265 procedures), and 15 because of parenchymal damage (1.2% of the 1265 procedures) (Table 4).

TABLE 3 Basic demographics on donors and procurement surgery.

Liver procurements (*n* = 1265)	
Mean age (IQR)	49.9 (42-61)
Mean BMI (IQR)	24.9 (22-27)
Night time procurement (%)	835 (66%)
Female (%)	633 (50%)
CVA and SAB cause of death (%)	708 (56%)
DCD (%)	426 (33.7%)
Liver only procurement (%)	451 (35.7%)
Liver pancreas en block (%)[a]	84 (39.3%)

Abbreviations: BMI, body mass index; CVA, cerebrovascular accident; DCD, donation after cardiac death; SAB, subarachnoid bleeding.
[a]214 liver pancreas were procured for pancreas transplantation purposes.

3.1 | C event (Surgical injured liver)

Parameter setting for CUSUM chart: p(0) rate was determined at .17 for both the national and local CUSUM graphs. This corresponded to the C event rate of 17% for the whole cohort. The p(A) was then subsequently calculated as .34. In the case of a C event, the CUSUM chart increased by .69 and in the case of no C event, the chart decreased by .23. Based on the simulation, a CL for alarm signaling of 3.5 for the CUSUM C event on national (false alarm after 1005 cases or 4 years and true alarm after 65 cases or 3 months) and a CL of 3 for the local level (false alarm after 565 cases or 11 years and true alarm after 55 cases or 1 year) was chosen (Table 1).

C event CUSUM charts: Nationally, the CL was reached multiple times during two distinct periods. The first period of consecutive CL trespassing corresponded to a period of 8 months (Sep 2012–Apr 2013). The second period was much shorter and covered a duration of 3 weeks (Dec 2014–Jan 2015). Thereafter the CL was never breached again

TABLE 4 Total incidence and types of surgical injuries (C-events) and incidence and types that led to discard of liver organs (C2-events) encountered.

Liver procurements (*n* = 1265)	%	*n*	% relative to total
C-event (*n* = 215; 17%)			
Arterial	42.8%	92	7.3%
Portal	2.3%	5	0.4%
Outflow	12.6%	27	2.1%
Inadequate flushing	5.6%	12	0.9%
Parenchymal tears	54.9%	118	9.3%
>1 injury per donor	15.8%	34	2.7%
C2-events (*n* = 24; 1.9%)			
Arterial	41.7%	10	0.8%
Portal	0.0%	0	0.0%
Outflow	12.5%	3	0.2%
Inadequate flushing	0.0%	0	0.0%
Parenchymal tears	62.5%	15	1.2%
>1 injury per donor	16.7%	4	0.3%

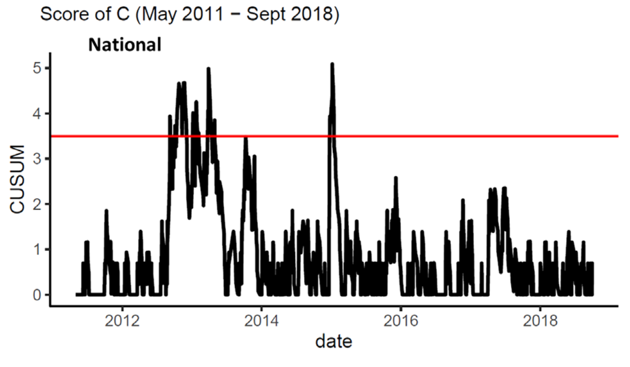

FIGURE 1 Unadjusted CUSUM for surgical injury of procured donor livers for the whole of the Netherlands from May 2011 until September 2018. The CL is crossed several times during 2 distinct periods (Sep 2012–April 2013 and Dec 2014 –Jan 2015).

from Jan 2015 onwards (Figure 1). Locally, two out of the five teams surpassed the CL while the three remaining teams continued to stay below the CL for the whole study period. Specifically, team I surpassed the CL during a single period of 13 months (May 2013 until June 2014) before spontaneous recovery, while team V surpassed the CL during two periods of 3.5 (Aug 2014–Dec 2014) and 10 months (Feb–Sep 2018), respectively (Figure 2).

3.2 | C2 (Discarded liver due to injury)

Parameter setting: A p(0) rate was determined at .019 which corresponded to an incidence of 1.9% discard rate of procured livers due to iatrogenic surgical injury for the whole cohort. The calculated p(A) was therefore .038. In the case of a C2 event, the CUSUM chart increased by .69 and in the case of a non-C2 event, the chart decreased by .02.

Based on the simulations, the investigators decided on a CL of 1.5 for the national CUSUM (FP after 515 cases or 4 years and TP after 125 cases or 6 months) and a CL of 1.1 for the local CUSUM charts (FP after 240 cases or nearly 5 years and TP after 80 cases or 17 months) (Table 2).

C2 event CUSUM charts: Nationally the CL was surpassed on three occasions for periods of 10 days (Jan-Feb 2012), 41 days (Feb-Mar 2013), and 11 days (May–Jun 2013), respectively. After Jun 2013 the CUSUM remained under the CL (Figure 3). Similarly, as in the aforementioned C CUSUM chart, two out of five local teams surpassed the CL for the discarded liver due to iatrogenic surgical injury on the local C2 CUSUM chart. Specifically, team I surpassed the CL in both CUSUM charts with the same overlap period as seen in both charts (May 2013-Feb 2014). Contrary to the C-CUSUM chart team V did not reach the CL in C2-CUSUM Chart. The other team that exceeded the C2-CUSUM's CL was team III. Team III surpassed the CL on four separate occasions. It returned below the threshold after the first three time periods of 205 days (Feb–Aug 2013), 202 days (Jan–Aug 2014), and 235 days (Nov 2014–July 2015), respectively, but remained well above the CL from Sep 2015 onwards after the fourth episode (Figure 4).

4 | DISCUSSION

Our retrospective study has shown that sequential monitoring with unadjusted CUSUM is feasible for a two-tier outcome analysis on a local and national level with meaningful conclusions. The two-tier system answers the questions whether the injury (C-event) automatically results in discard of organs (C2-event), as well as on which level this issue is present (local vs. national procurement team). This could potentially save time by directing necessary measures at the right level because of the increased awareness. The next step would be to

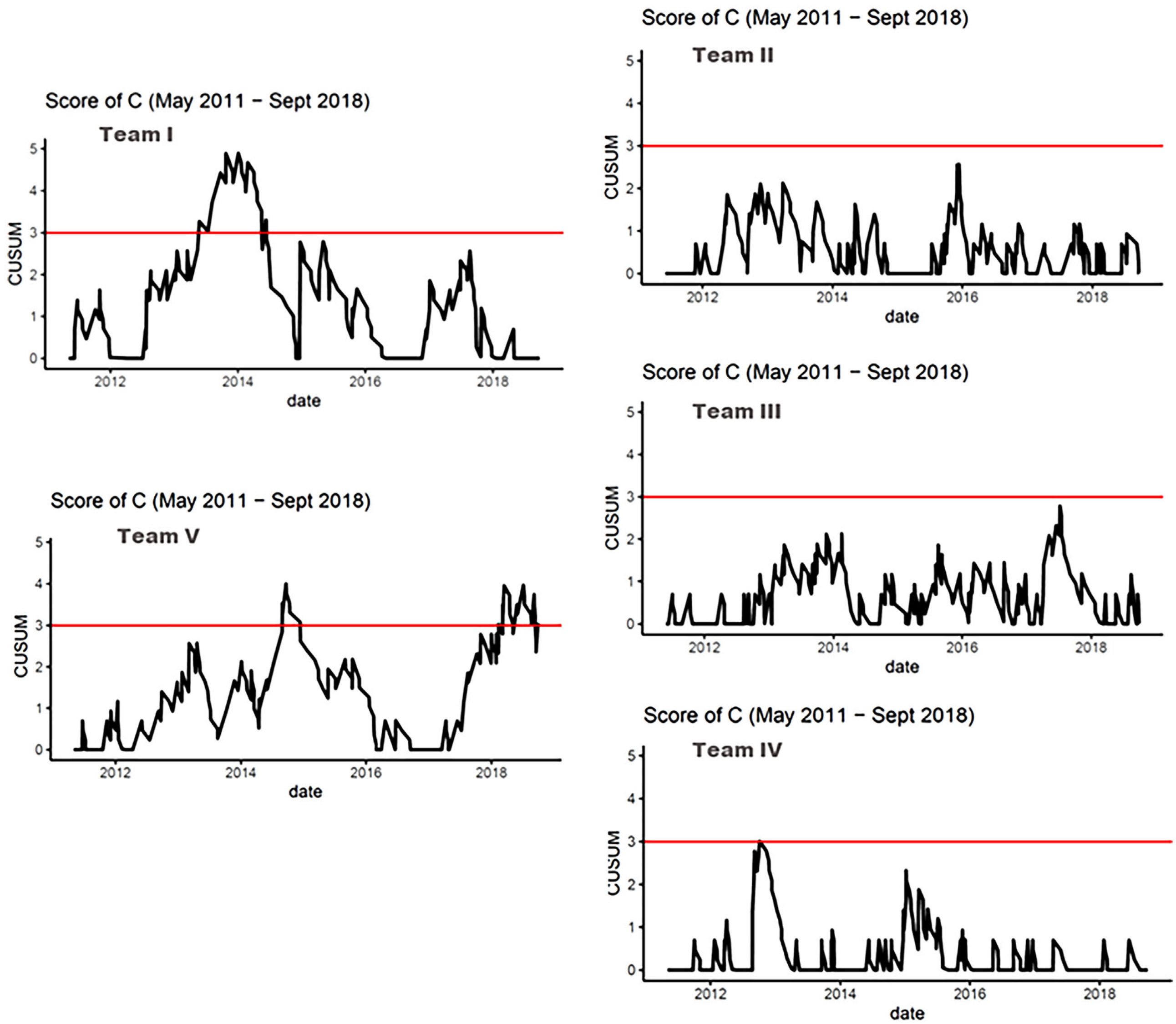

FIGURE 2 Unadjusted CUSUM for surgical injury of procured donor livers by the individual local teams from May 2011 until September 2018. The CL is crossed several times in two teams (Team I and V).

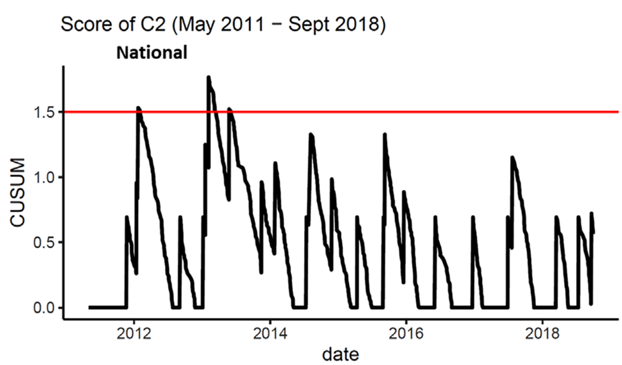

FIGURE 3 Unadjusted CUSUM for discarded livers due iatrogenic surgical injury (C2) for the whole of the Netherlands from May 2011 until September 2018. The CL is crossed three times (Jan–Feb 2012, Feb–Mar 2013 and May–Jun 2013).

implement the method in a prospective manner via an online secured dashboard, only accessible to the monitoring authority as well to the local teams. Implementing such a monitoring system in a prospective manner requires time, manpower and IT resources, but the cost of saving patients from dying on the waiting list would justify this, according to our retrospective analysis.

Abdominal procurement in the Netherlands is delivered by regional surgical teams rather than surgeons from centres accepting the organs. There are a total of three regions, with geographic five local procuring teams, taking this responsibility of procuring safely for the center that accepted these organs. This advantage of cost-efficiency, by keeping logistics and transport costs to a minimum, requires on the other hand a certain trust from the transplant center. These cents rely on these local procuring surgical teams to get them the necessary livers with as little as possible surgical damage. The certification process,

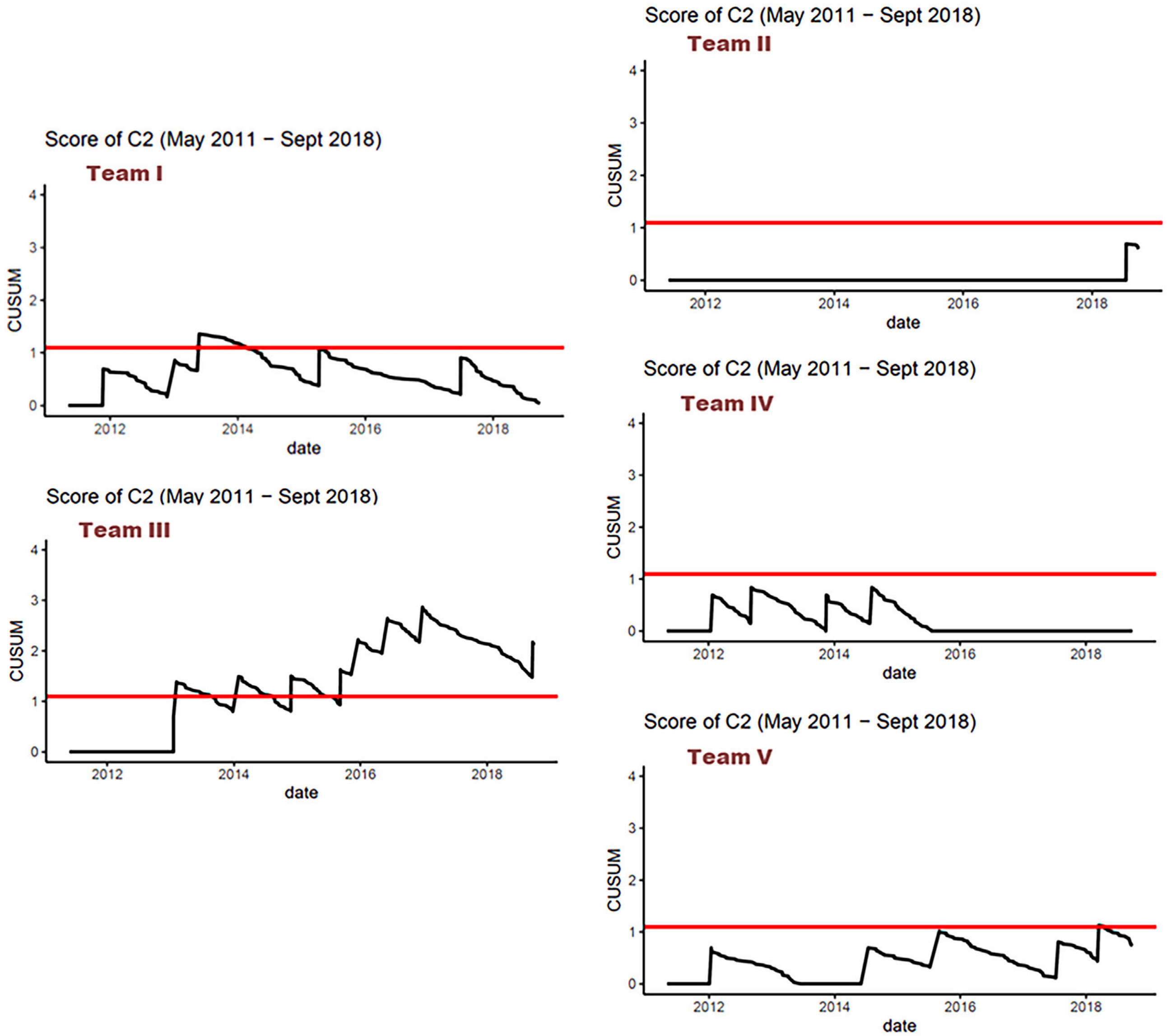

FIGURE 4 Unadjusted CUSUM for discarded liver due to iatrogenic surgical injury (C2) after procurement for local teams from May 2011 until September 2018. The CL is crossed several times in two teams (Team I and III).

direct feedback and standardization of the procedure has helped in the past in building this trust, but a real-time monitoring tool could further aid in adding more confidence and transparency. This is especially the case if accepted benchmark of iatrogenic injury rate for liver organ procurement are well known and continuously monitored. Our analysis has shown that the injury rate of procured livers in the Netherlands has improved remarkably to an incidence of 17% (C event) from this first report in 2006[10] and reports from United Kingdom seems to show similar incidence of injury in liver procurement.[11] This is a further indication that training with certification,[1] the use of a digital surgeon feedback system (quality forms) and the establishment of LORUT as the national governing body have made a positive impact in the Netherlands in saving unnecessary loss of suitable/acceptable liver organs for transplantation. Further improvement in real time awareness is necessary to potentially limit unnecessary organ lost due to iatrogenic damage. This should in turn lead to decreased mortality for patients on the waiting list and improved transplantation outcome.[10] Real time awareness by using a sequential monitoring tool, such as CUSUM, has already led to improvement in individual surgical performance in cardiac surgery for instance.[12]

Unadjusted CUSUM in monitoring outcome in the transplantation field is statistically relatively easy to plot based on a binary outcome as it's being currently applied in various national transplant programs.[4–6] In our study, this binary outcome was the incidence of a C- or C2-event. Only a very limited dataset (chronological C- and C2 events by each individual team only) was necessary for this analysis, as no risk model was needed to develop the unadjusted CUSUM graph. It's relative ease and simplicity is an advantage over risk adjustment especially if independent risk variables need to be pre-established and maintained since practical circumstances and donor population might change over time.

Real-time quality control by only looking at alarm signaling or CL is then the only thing needed when the monitoring tool has been established. The CL only defines the choice of what is acceptable by the monitoring authority and can be adapted based on the realistic field case numbers per year as was in our case. If we set the alarm too low then we would be dealing with more false alarms and if we set this horizontal line too high it might completely prevent any alarm triggers. Our alarm choice was based on this balance taking into account the caseloads. The national choice of CL was therefore stricter then the local teams given the lower caseloads on the local level. National alarming should also be more concerning as it would need more effort to correct (i.e., training, governmental, financial, logistical, etc.) then local team changes (individual performances). A last point is that on a local level false alarming with unfair correction can lead to demotivation and misunderstandings so thoughtful care must be applied when choosing a balance between false and true alarm signaling.

When looking at individual CUSUM graphs that besides signaling an alarm, CUSUM charts can also point to specific timeframes with suboptimal performance if no corrective measures were undertaken once the alarm was surpassed or as in our case when it is applied retrospectively. In an ideal situation, as a prospective real-time monitoring tool, once the alarm has been passed the CUSUM needs to be restarted after corrective measures have taken place. The value at which a CUSUM needs to be reset remains a further point of discussion. Starting at zero would mean things are normal again and whether this needs to be the case when a team has been red flagged and under close observation remains a further point of discussion by the transplant community and/or monitoring authority. However, due to our retrospective nature of our analysis and the lack of measures after alarming has taken place, it is a pleasant surprise to see that in six of the alarmed CUSUM charts with the exception of one, the duration of surpassing the CL was self-limiting and the CUSUM returned below the threshold again on more than one occasion, further questioning whether a reset or implementing corrective measures is not always justifiable. The reason for this return to below the CL remains to be investigated but instant negative feedback through the quality forms by the transplant surgeons might increase the bad performance realization and consequent increased attention towards the alerted issues. However, this was not always the case as one CUSUM chart showed absence of getting under the CL in time (Figure 4). At a first glance, the C-CUSUM chart for this specific team (Team III) showed no alarming signal in injury rate (Figure 2), but the C2 chart showed abnormal continuous incremental alarming (Figure 4), which indicates a real problematic performance in terms of potentially livers lost as they were probably not aware given the very low incidence of C2 on the whole. The inverse applies to team V where C-charts showed alarming without C2 charts alarming. This further strengthens the argument for a two tier real-time surveillance system separately for surgical injury rate and discard rate respectively as correlation between the two events is not always present.

A second interesting finding is the discrepancy between national and local CUSUM charts. National detrimental performance was not reflected in the local team CUSUM charts at the same point in time and vice versa. Furthermore, a national CUSUM chart is not a simple statistical sum of the five local CUSUM charts at any given point in time. This is especially demonstrated by the two national CUSUM charts (C and C2 events). Herein, a less than ideal performance in late 2012 until the beginning of 2013 was seen which was not reflected in any of the local team's CUSUM charts. It was expected that teams I and V had the same overlap alarm time points as the national C-CUSUM graph. The same was to be expected on the C2 CUSUM graphs for teams I and III overlapping the national one, but this was not the case. These findings suggest that national changes impact all teams, whereas changes in local teams do not impact other teams performance and have limited impact on the national CUSUM. The possible learning curve with a higher influx of new certified surgeons during the 2011 period, exponential increase in DCD procurements and the start of using digital quality forms as a direct instant assessment tool from the transplant surgeons are all valid possible reasons behind the national surge as seen on the national CUSUM charts and remain to be investigated. On the other hand, local changes in any particular team such as new team members, changed team dynamics, different team protocols, personal fatigue can only have consequences for the concerned team with little or no concern for the other teams for this matter. This further accentuates the importance of plotting both a CUSUM nationally and on a local level in the monitoring processes as it can better direct the corrective measures needed at the right level.

As discussed before, an unadjusted CUSUM without risk adjustment is fairly straight forward to plot with meaningful results. The question remains whether it reflects the real world as no two cases are ever the same, contrary to the industrial process. The unadjusted CUSUM does not take independent risk factors into account should such an event take place. A high-risk case should in fact be less penalized versus a low risk case as in all types of surgery and complication data analysis. Plotting a risk-adjusted CUSUM is more challenging as it requires more data, more advanced statistical methods, choosing an ideal risk model among the many different types available, and more importantly including as many as possible independent risk-factors which would making an ideal risk model very challenging. For instance, it is known that two out of the five local procurement teams have also experience in the liver transplantation recipient operation. It has been shown in pancreas procurement, that if teams have pancreas transplant experience, organ injury and discard rate is reduced,[1,2,13] Yet, for liver transplantation this remains to be elucidated. Another important consideration is the impact of on alarming risk adjusted CUSUM would actually have to the corresponding individual unadjusted CUSUM plots. Furthermore, if this change in alarming is limited compared to the unadjusted CUSUM chart then would it be justified to add a risk-adjusted CUSUM graph to complicate monitoring processes? The Netherlands is a country with a homogenous donor population where environmental and cultural differences are limited. Also, the variation between surgical experience and local team dynamics are kept to a minimum because of the same logistics, national rigorous practical training and certification process as the mandated National curriculum prescribes the standard way of abdominal procurement regardless of liver transplant background.[1] Because of this, we believe that the impact of risk adjustment might not be as pronounced as expected. Nevertheless, it remains to be investigated in the near future.

In conclusion, unadjusted local and national CUSUM plots for injured procured donor livers (C event) and discarded injured donor livers (C2 event) could be a valuable simple tool to prospectively monitor surgical quality in organ retrieval in a real-time manner. This could save unnecessary organs lost and more patients on the liver transplant waiting list transplanted, leading to further quality improvement.

AUTHOR CONTRIBUTION

Lam Hwai-Ding MD[a] : Principal author, designed the study and wrote the paper. Schaapherder Alexander F MD PhD[a]: Participated in the performance of the research and participated in the writing of the paper. Alwayn Ian PJ MD PhD[a] : participated in the writing of the paper. Nijboer Willemijn N MD PhD[ac] : participated in the writing of the paper. Tushuizen Maarten E MD PhD[d] : participated in the writing of the paper. Hemke Aline C PhD[e] : participated in the performance of the research and participated in the writing of the paper. Baranski Andrzej MD PhD FEBS[a] : participated in research design in the performance of the research and in the writing of the paper. Van der Pas Stéphanie L PhD[b] : participated in data analysis, research design in the performance of the research and in the writing of the paper.

CONFLICT OF INTERESTS STATEMENT

The authors declare and have no related conflicts of interest and no funding was involved in this study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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