

Original Article

Unrestricted drinking before surgery: an iterative quality improvement study

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Summary

Average pre-operative fasting times for clear liquids are many times longer than those specified in national and international guidelines. We sought to decrease fasting times by applying a quality management tool aimed at continuous improvement. Through the application of iterative 'plan-do-study-act' cycles, tools to reduce pre-operative liquid fasting times were developed and applied, the effects measured, analysed and interpreted and the conclusions used to inform the next plan-do-study-act cycle. The first step was the introduction of unrestricted drinking until the patient was called to the operating theatre, with training of anaesthetic staff, adaptation of local standard procedures and verbal information for patients. This did not result in short liquid fasting times, median (IQR [range]) 12.0 (9.5–14.0 [0.8–23.5]) h. In the second cycle, fasting cards were introduced as a subliminal written training tool for staff, patients and their relatives. This enabled short liquid fasting times to be achieved for outpatients (2.6 (0.8–5.1 [0.3–16]) h) and pre-admission patients (3.4 (1.8–9.4 [0.2–17.2]) h), but not for inpatients (6.5 (2.0–11.7 [0.2–16.2]) h). The third cycle included lectures for ward staff, putting up information posters throughout the hospital, revision of all written materials and provision of screencasts on the homepage for staff and patients. This decreased median liquid fasting time to 2.1 (1.2–3.8 [0.4–18.8]; $p < 0.0001$) h, with inpatients having the shortest fasting time of 1.4 (1.1–3.8 [0.4–18.8]) h. Repeated quality improvement cycles, adapted to local context, can support sustained reductions in pre-operative liquid fasting times.

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Introduction

Patients who undergo procedures that can cause depression of protective reflexes, such as sedation or anaesthesia, are advised to follow fasting recommendations to minimise the risk of pulmonary aspiration. For clear liquids, international guidelines recommend a 2-h fasting period for adults [1, 2]. In many hospitals, especially those providing emergency care, this requirement is not organisationally feasible when trying to ensure efficient utilisation of operating theatre time. Patients typically fast

for clear liquids for an average of 6–10 h pre-operatively [3–6]. Prolonged liquid fasting periods not only impact on patient well-being, but can also cause severe postoperative complications.

There have been several approaches to reduce fasting times. Education and training reduced the mean time of liquid fasting in adults from 11 h to 5 h in one study [7]. Removal of the traditional 'nil by mouth from midnight' instructions, patient education, a clear fasting routine with pre-operative drinks and improved communication

between the full multidisciplinary team led to a similar reduction in fasting times from 16.3 h to 5.1 h in adults [8]. Within the framework of a quality management project with about 16,000 children, the introduction of a 1-h liquid fasting limit reduced the average liquid fasting time from 9 h to 6 h [9]. When children were allowed to drink clear liquids until called to the operating theatre, the mean liquid fasting time decreased from 4 h to 1 h [10, 11].

We hypothesised that a quality management tool focused on continuous improvement would be able to substantially reduce liquid fasting times. 'Plan-do-study-act' (PDSA) cycles provide a structure for iterative testing of changes to improve quality of systems. The method is widely accepted in healthcare improvement [12]. Our study aimed to reduce the pre-operative liquid fasting time as close as possible to the guideline recommendation by applying PDSA cycles.

Methods

The study protocol was approved by the ethics committee of Helios Emil von Behring, Berlin. Within the framework of quality management, no pre-registration as a clinical trial and no separate patient information and informed consent were required.

Helios Klinikum Emil von Behring is an academic teaching hospital of Charité Berlin, with over 500 beds and more than 10,000 anaesthetics given annually. Partly as a consequence of emergency procedures and rescheduling, the operation schedule changes frequently during the course of the day. This leads to difficulties when trying to adhere to pre-operative liquid fasting guidelines.

At the time of our study, pre-operative clear liquid fasting times far exceeded the recommended 2 h [1, 2] and most of our patients stated that the last time they drank anything was the evening before surgery. For maximum flexibility in operating theatre management, and to preclude cancellation in the absence of fasting (e.g. if surgery was brought forward in time), patients remain fasting from at least the early morning hours, regardless of their scheduled time of surgery. This resulted in liquid fasting times of 12 h and longer.

As part of a continuous quality improvement effort, we aimed to solve this problem by developing a new fasting concept for clear liquids using iterative PDSA cycles. The PDSA cycle represents a pragmatic scientific method for problem solving and continuous improvement in complex systems. The four phases reflect the scientific process of planning a change ('plan'), implementing that change ('do'), analysing and interpreting the results ('study'), and drawing

conclusions to inform the next cycle ('act'). Ineffective changes contribute to learning processes, which is a basic principle of the PDSA cycle. These cycles only work if they are understood as a learning process. The findings from each PDSA cycle must be carefully analysed and compared with the theoretical background. All staff members should be encouraged to be clear in reporting formal and informal theories, models, concepts or even hunches as to why they expected a particular intervention to work in a particular context [13]. This allows a motivated team to transform an idea into a clinical improvement through iterative PDSA cycles [12].

All procedures introduced in this quality management project applied to all patients of the hospital. After evaluating the data from each cycle, further procedures were decided and introduced. All procedures applied in the individual cycles are fully described in the results.

The main team involved in this project comprised a medical specialist who was responsible for study conception and implementation and the head of department who collaborated on study concept, established the 'non-rejection-policy' with the staff and took responsibility for the differences between local guidelines and national guidelines.

Data analysis was performed using Excel 2019 (Microsoft, Redmond, WA, USA) and SPSS V28 (IBM Corporation, Chicago, IL, USA). In the absence of a normal distribution, liquid fasting times are presented as median values. The comparison of liquid fasting times between groups was performed using the Mann-Whitney U test. No corrections were made for repeated tests.

Results

Patient characteristics are listed in Table 1. Figure 1 shows the iterative PDSA cycles to reduce clear liquid fasting times, and these are further outlined below.

Cycle 1

Plan: Conduct a literature review on approaches to shortening fasting times. The decision was made to introduce the concept of unrestricted drinking until called to the operating theatre for all patients, which has been used successfully with children since 2000 [10].

Do: In the summer of 2018, the liberal fasting concept was introduced in our hospital. It allowed all adults and children scheduled for elective procedures to drink clear liquids until called to the operating theatre or for examination. All team members in the anaesthesia department were trained and local standard procedures

Table 1 Patient characteristics before and after implementation of fasting cards. Data are number (proportion) or median (IQR [range]).

	Before n = 270	Weeks 3 and 4 n = 156	Week 25 n = 143
Sex; male	127 (47%)	82 (53%)	77 (54%)
Age; y	59 (41–71 [2–93])	59 (32–74 [1–87])	57 (43–70 [2–91])
Adults	243 (90%)	133 (85%)	125 (87%)
Children	27 (10%)	23 (15%)	18 (13%)
Time of surgery			
Before 11.00	196 (73%)	102 (65%)	78 (55%)
After 11.00	74 (27%)	54 (35%)	65 (45%)
Patient status			
Inpatient	118 (44%)	44 (28%)	57 (40%)
Pre-admission patient	106 (39%)	96 (62%)	68 (47%)
Outpatient	46 (17%)	16 (10%)	18 (13%)

were adapted. Patient education was provided verbally during the pre-anaesthesia interview. Ward staff received a note on the anaesthesia record for each patient.

Study: In early 2021, 270 elective patients were asked about the timing and amount of their last liquid intake just before induction of anaesthesia or sedation. The median liquid fasting time regardless of the amount of liquid ingested was 2.4 h. But if patients were asked about only liquid intake of more than a few sips of water (e.g. to take medication), the median (IQR [range]) fasting time was 12.0 (9.5–14.0 [0.8–23.5]) h.

Act: Unfortunately, giving permission for unrestricted drinking until called to the operating theatre did not result in short liquid fasting times. Evaluation of further concepts led to the decision to introduce additional educational interventions, which some study groups have used to achieve shorter liquid fasting times [7, 8]. As we accepted shorter fasting times than those specified in guidelines with our unrestricted drinking until called to the operating theatre approach, we decided to use fasting cards. These allow an individualised approach for each patient and thus may increase patient safety. At the same time, they provide good training for hospital staff, patients, and their relatives [14].

Cycle 2

Plan: Planning for the introduction of fasting cards included adapting the originally described cards to local conditions, printing fasting cards as A5 (148 mm × 210 mm) paper flyers and producing laminated A4 (210 mm × 297 mm) fasting cards (Fig. 1). Hospital staff were informed through training, emails and individual contacts.

Do: During the anaesthesia consultation, each patient was assigned one of three fasting cards (Fig. 2): green card

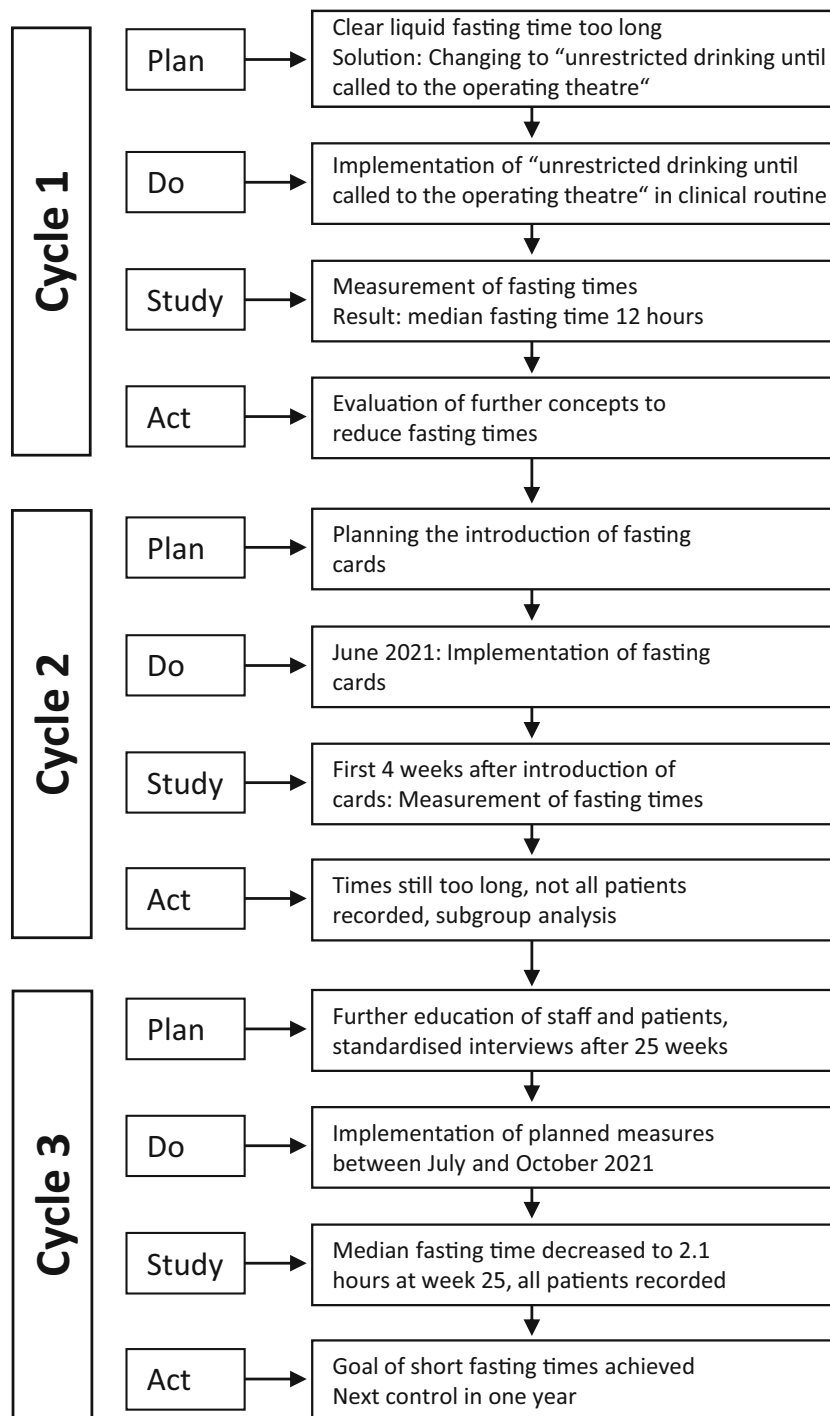
– patients are allowed to drink clear liquids, as well as tea and coffee, with honey, sugar and/or some milk if desired, until they are called to the operating room or for intervention; yellow card – for patients who are subject to stricter rules, the fasting times for liquids and solid food can be determined individually; and red card – for patients who must remain fasting from the time of indication for surgery or examination.

Patients with pre-existing conditions that may promote delayed gastric emptying (e.g. diabetes, gastroparesis, reflux, achalasia, hiatus hernia) were required to observe 2-h liquid fasting only if they reported regurgitation or relevant coughing attacks while lying down. Information is provided in German on the front of the cards, and in English, Turkish, Russian and Arabic on the back (online Supporting Information, Appendix S1).

Elective inpatients are given a laminated fasting card to hang by their bed. Outpatients and pre-admission patients receive a fasting card as a paper flyer to take home. Emergency patients receive a fasting card in the Emergency Department, depending on their diagnosis and the urgency of their surgery. For example, a patient with ileus receives a red card. A patient waiting for surgery with a hip fracture receives a yellow card and is not allowed to eat, but allowed to drink until called to the operating theatre. A patient who will not be examined or operated until the next day will receive a green card. Fasting cards can be used for all patients before anaesthesia or sedation, for example also before transthoracic echocardiography, bronchoscopy or gastroscopy.

Study: In the first 4 weeks after the introduction of the fasting cards, patients were asked by the anaesthesia nurse immediately before induction about the time and amount of intake of clear liquids. Median (IQR [range]) liquid withdrawal times gradually decreased: 1st week, 8.7

Figure 1 Flowchart of plan-do-study-act cycles to reduce pre-operative liquid fasting times.



(2.0–12.8 [0.1–23.3]) h (n = 72); 2nd week, 5.7 (2.0–11.8 [0.4–18.3]) h (n = 92); 3rd week, 3.7 (1.4–9.9 [0.2–17.2]) h (n = 79); 4th week, 3.7 (1.8–10.0 [0.2–16.8]) h (n = 77).

Act: Liquid fasting times were documented for only half of the patients. A subgroup analysis of the data from the 3rd and 4th week showed that inpatients fasted the longest, with a median (IQR [range]) of 6.5 (2.0–11.7 [0.2–16.2]) h. For outpatients, the median was 2.6 (0.8–5.1 [0.3–16]) h and for

pre-admission patients the median was 3.4 (1.8–9.4 [0.2–17.2]) h (Fig. 3).

Cycle 3

Plan: To reduce liquid fasting times for inpatients in particular, the following further education and information dissemination measures were planned and prepared: lectures for the ward staff, hanging of information posters



Figure 2 Fasting cards green, yellow and red.

throughout the hospital with a photo of the study team (“*Drinking until shortly before the operation is even encouraged here!*”), revision of all written materials/letters/flyers/information on the website and provision of screencasts on the homepage for staff (intranet) and patients (internet).

Do: Implementation of the planned measures took place between July and October 2021.

Study: A follow-up after 25 weeks included all patients who were scheduled to have an elective procedure under anaesthesia care within one calendar week and were able to

answer questions (or parents on behalf of children). Of 149 patients, three adults with dementia and three children with learning disabilities were unable to answer all questions. Therefore, 143 patients were included in the study and interviewed in a standardised way by the same person (AR). At 25 weeks after the introduction of fasting cards, the median liquid fasting time decreased to median (IQR [range]) 2.1 (1.2–3.8 [0.4–18.8]) h; $p < 0.0001$ (Fig. 3), with inpatients having the shortest fasting time of 1.4 (1.1–3.8 [0.4–18.8]) h. The proportion of patients who had been drinking within the last 4 h before induction of anaesthesia increased from 12.2% before the introduction of fasting cards to 79.7% 25 weeks after the introduction of fasting cards. The proportion of patients who had been fasting for more than 10 h decreased from 67.8% to 5.6% (Fig. 4). There was no difference in median liquid fasting time between patients in the first position in the surgical schedule (1.96 h), those starting anaesthesia before 11.00 (2.08 h) or patients after 11.00 (2.0 h). The main reasons for liquid fasting for more than 4 h included the following: patient did not want to drink ($n = 6$); patient was not informed or did not understand the information ($n = 5$); patient was not sure if they were allowed to drink despite being informed ($n = 4$); patient was afraid of urination ($n = 4$); or the patient was not given anything to drink on the ward ($n = 2$).

Act: The goal of a short liquid fasting period was achieved in most patients.

Discussion

Within the framework of a quality management tool with three iterative PDSA cycles, the median liquid fasting time was reduced from 12 h to 2.1 h. The concept developed included a liberal liquid regime with unrestricted drinking until called to the operating theatre and its implementation using fasting cards. The fasting cards enabled an individually-adapted procedure for each patient, with simultaneous subliminal training of the hospital staff, patients and their relatives. However, understanding why this approach worked is crucial for further implementations in other hospitals. Simply copying our approach without understanding the rationale and context is unlikely to succeed.

In the first PDSA cycle, unrestricted drinking until called to the operating theatre was implemented and seemed to work in clinical routines. However, as already described by Dixon-Woods [15], a supposedly positive change often does not stand up to rigorous evaluation. This was also the case in our hospital: the desired short fasting times were practically non-existent. A more in-depth evaluation of the

Figure 3 Patient status and fasting duration before (n = 270), at weeks 3 and 4 (n = 156) and at week 25 (n = 143) after implementing fasting cards. Line is median, cross is mean, box is IQR, whiskers are 1.5 × IQR and points are outliers. Light grey, before; striped, weeks 3 and 4; dark grey, week 25.

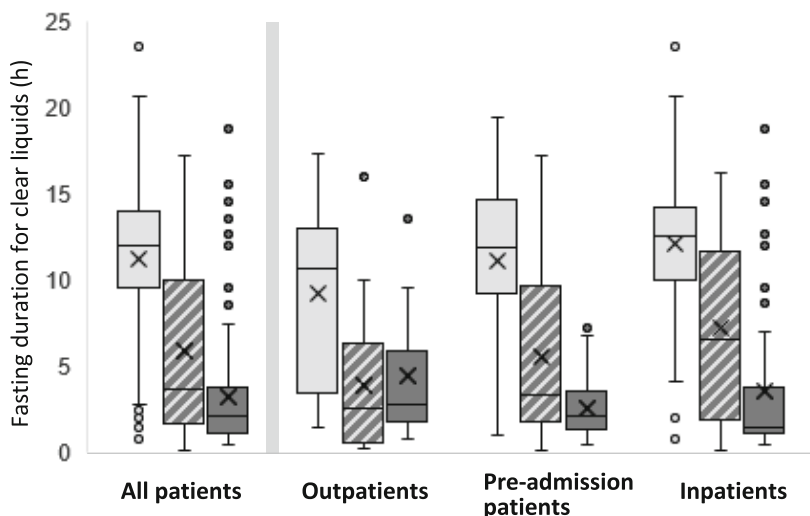
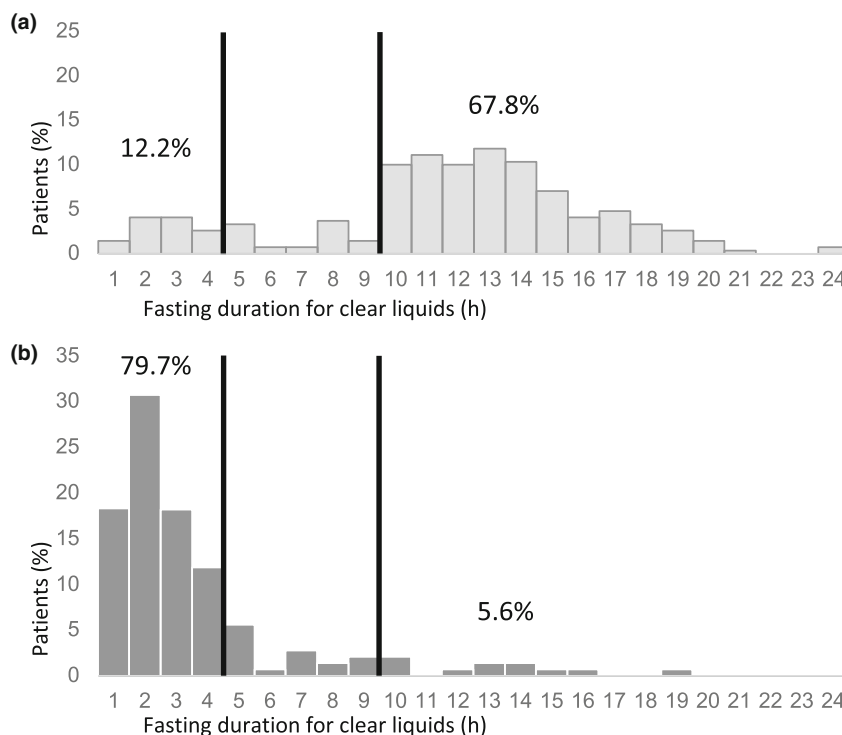


Figure 4 Distribution of fasting times (a) before (n = 270) and (b) 25 weeks after (n = 143) implementation of fasting cards.



amount of liquid drunk (‘more than a few sips of water’) demonstrated very long liquid fasting times of a median of 12 h. At the end of the first cycle, the decision was made to introduce fasting cards. Within 3 weeks, the median liquid fasting time was reduced from 12 h to 3.7 h and remained at this value in the 4th week. However, inpatients still had the longest liquid fasting times, with a median of 6.5 h. Based on these data, targeted measures to reduce liquid fasting times in inpatients were developed for the third PDSA cycle. At the end of the third cycle, inpatients had the shortest

liquid fasting time at 1.4 h. However, pre-admission patients, who were admitted to hospital on the day of their operation, had also benefited from the interventions, with liquid fasting time decreasing from 3.4 h to 2.2 h. The analysis and interpretation of the results of each cycle thus enabled learning for the following cycle and targeted measures to further reduce the pre-operative liquid fasting time. However, this means that almost half of patients do not adhere to the 2-h clear liquid fasting time recommended in the guidelines [1, 2].

Soft factors and tactics have contributed to success in other projects, such as the Michigan Keystone Project [16, 17], and we suggest the following factors were important to the success of our project.

First, a strong team leader is needed. In our case, whenever a problem arose, the project leader immediately asked for the reasons, listened carefully and worked out a solution with all those involved. Mainly organisational problems were discussed. Repeated problems were solved through additional education. Strong leadership by the team leader was *“recognized by their peers as committed, credible, and engaging, and to communicat[ing] a sincere belief in the program [with] enough listening to ensure peers felt heard, but also know when to push it ‘hard’”* [17]. With the poster campaign, we gave the team leader a ‘face’ that was omnipresent throughout the hospital. While it took a lot of effort to convince the staff, it was easier to convince our patients, as they welcomed the invitation to drink.

For PDSA cycle 2 (introduction of fasting cards), we started simultaneously in all surgical departments with joint team meetings and several presentations, including individual departments and the whole hospital. Through this focused approach, we tried to create isomorphic pressure (the desire to conform to group norms) among participants. By swapping nursing staff, e.g. through temporary staff or pool staff, we were able to distribute the pressure to conform across the wards. Currently, this is reinforced by the introduction of fasting cards also for procedural sedation.

A success factor in previous projects appears to be the creation of *“a densely networked community, with strong links between units, encouraged by regular meetings and communication, that reinforced these norms and enabled sharing of information”* [17]. Due to variation in our healthcare system, we are trying to establish this with further clinics adopting the fasting cards solution. The first five pilot clinics have treated several thousand patients according to the concept unrestricted drinking until called to the operating theatre with fasting cards and have all had very good experiences. Several talks have been given and nationwide presentations and lectures are coming up, hopefully strengthening the links between hospitals and teams.

Furthermore, collecting data systematically and utilising it is crucial, since data can be strongly motivating if collected in the right way. Two effects can occur if data are not collected systematically: if patients are asked for the ‘last sip’, fasting durations are short, hence the real problem of relevant liquid fasting is undetected and the intervals are taken as evidence that no change is needed. Alternatively,

long fasting times are dismissed as poor quality data, again leading to the view that no change is needed.

It seems to be just as important to present this problem in such a way that it can be solved through grassroots activism. For this purpose, not only doctors, but nurses and service staff were trained and empowered to determine fasting cards according to fixed criteria, even without a formal doctor’s order. In this way, a social movement was created in which all participants wanted to relieve the patient’s thirst, thus creating the feeling that everyone could participate in solving the problem.

The described PDSA cycles consisted of different interventions which may have functioned in different ways but aiming jointly to reduce fasting times. However, we think of the introduction of the fasting cards as the central mechanism.

Disregarding national and international guideline recommendations was the main reason for difficulties in introducing unrestricted drinking until called to the operating theatre. Many nurses found it difficult that for decades they had to forbid their patients to drink before surgery and now patients are even encouraged to drink. Frequent staff changes also made it difficult to implement new concepts. For this reason, liquid fasting times could be reduced much faster in outpatients and pre-admission patients than in inpatients.

The deviation from the guideline recommendations was also present for patients. Some patients appeared unsure when asked about their drinking behaviour on the day of surgery – *“Does the interviewee know that they are allowed to drink?”* Therefore, during the standardised interview, patients were first asked whether they had received a fasting card and, if not, whether they had been informed that they were allowed to drink. As not all staff members at our clinic were willing to ask these additional questions, we were unable to introduce continuous recording of fasting times. Instead, once a year we will record the liquid fasting times of all patients in a certain period.

With the introduction of unrestricted drinking until called to the operating theatre, our project started with a procedure that causes many anaesthetists to refuse to induce anaesthesia. There is neither evidence nor a pathophysiological explanation that shorter liquid restriction times of < 2 h are harmful. Current adult guidelines only cite studies that investigated liquid fasting times between 2 and 4 h vs. > 4 h or conclude that drinking up to 2 h before induction of anaesthesia has no effect on or even reduces gastric residual volume [1, 2].

Besides the medicolegal aspect, the main reason for strict adherence to fasting limits [1, 2] is the fear of

pulmonary aspiration. However, aspiration of liquids is extremely rare, especially in elective patients, and is usually associated with a rapid recovery [18–20]. Pre-existing conditions are not an independent risk factor for aspiration [19]. In contrast, most aspirations are due to the failure to recognise risk factors for aspiration and to adjust the anaesthetic technique accordingly [20–22]. Therefore, the current international multidisciplinary consensus statement recommends that all patients who are at no or low risk of aspiration should be allowed to consume clear liquids without restriction before procedural sedation [23]. In contrast, prolonged liquid fasting not only causes discomfort such as thirst, but is associated with postoperative complications including delirium in the recovery room and on the ward [6].

The acceptance of the fasting cards is high [14]. A previous evaluation of the introduction of fasting cards in another institution demonstrated that 8 months after their introduction, ward managers were in favour of patients drinking clear liquids until called to the operating theatre and almost all were in favour of implementing this concept using fasting cards. Nine out of 11 ward managers perceived patients waiting for their operation as more relaxed and intravenous liquid substitution was requested less frequently. Without exception, all ward managers would have liked to be managed according to the new unrestricted drinking until called to the operating theatre concept were they themselves to undergo surgery [14].

However, some limitations may exist, e.g. the application of PDSA cycles is influenced by local conditions [12]. Therefore, the concept of unrestricted drinking until called to the operating theatre and the implementation by means of fasting cards is adapted to the specific process flows in our hospital. The soft factors and tactics described may be crucial, since change may be seen as a big threat. It may be perceived as “*what you have done so far may be wrong*” or “*people do not appreciate what you have been doing for the last years*” [17]. Implementation strategies need to create the right conditions and change needs to be implemented with commitment to lead to significant improvements. This requires staff who consistently drive the project forward with a great deal of enthusiasm, power and persuasion.

In conclusion, after three iterative PDSA cycles, median liquid fasting times were reduced significantly and in a sustained fashion. Fasting cards allow an individualised approach for each patient, potentially increasing patient safety. The learning effect of individual training measures, especially if the content violates lived routines and guidelines, quickly disappears. In contrast,

the fasting cards are present on a daily basis and thus function as an endless subliminal training tool and reminder. The unrestricted drinking until called to the operating theatre concept allows patients to continuously drink clear liquids during the day of surgery without limiting the flexibility of the surgical schedule. Any time or quantity limitations regarding pre-operative liquid fasting poses organisational challenges for hospitals. Especially when non-compliance with a time limit results in a cancellation of an operation; for the sake of simplicity, people like to fall back to uniform fasting beginning in the early morning hours. Therefore, a corresponding revision of the guideline recommendations on liquid fasting before anaesthesia would be desirable.

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Supporting Information

Additional supporting information may be found online via the journal website.

Appendix S1. Fasting cards in English, German, Turkish, Russian and Arabic.