A Quality Improvement Project to Increase Breast Milk Use in Very Low Birth Weight Infants

AUTHORS: Henry C. Lee, MD, MS,^{a,b} Paul S. Kurtin, MD,^c Nancy E. Wight, MD, IBCLC,^d Kathy Chance, MD,^e Tracey Cucinotta-Fobes, RN, BSN, RNC, IBCLC,^f Tara A. Hanson-Timpson, RD, IBCLC,^g Courtney C. Nisbet, RN, MS,^b William D. Rhine, MD,^h Kate Risingsun, RN, IBCLC,^f Matthew Wood, PhD,ⁱ Beate H. Danielsen, PhD,^j and Paul J. Sharek, MD, MPH^{b,k,l}

^aDivision of Neonatology, Department of Pediatrics, University of California, San Francisco, San Francisco, California; ^bCalifornia Perinatal Quality Care Collaborative, Stanford, California; ^cDepartment of Quality Management, Rady Children's Hospital, San Diego, California; ^dSharp Mary Birch Hospital for Women and Infants, San Diego, California; ^eChildren's Medical Services Branch, California Department of Health Care Services, Sacramento, California; ^fSutter Medical Center, Sacramento, California; ^gSharp HealthCare, San Diego, California; Divisions of ^hNeonatal and Developmental Medicine and ⁱGeneral Pediatrics, Department of Pediatrics, Stanford University School of Medicine, Palo Alto, California; ^jDepartment of Analytics and ^kCenter for Quality and Clinical Effectiveness, Lucile Packard Children's Hospital, Palo Alto, California; and ^lHealth Information Solutions, Rocklin, California

KEY WORDS

breast milk, very low birth weight infants, quality improvement

ABBREVIATIONS

CCS—California Children's Services

CPQCC—California Perinatal Quality of Care Collaborative

NEC—necrotizing enterocolitis

VLBW—very low birth weight

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Address correspondence to Henry Lee, MD, Department of Pediatrics, Division of Neonatology, University of California, San Francisco, 533 Parnassus Ave, Room U503, San Francisco, CA 94143-0734. E-mail: hank45@gmail.com

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abstract

OBJECTIVE: To evaluate a multihospital collaborative designed to increase breast milk feeding in premature infants.

METHODS: Eleven NICUs in the California Perinatal Quality of Care Collaborative participated in an Institute for Healthcare Improvement-style collaborative to increase NICU breast milk feeding rates. Multiple interventions were recommended with participating sites implementing a self-selected combination of these interventions. Breast milk feeding rates were compared between baseline (October 2008–September 2009), implementation (October 2009–September 2010), and sustainability periods (October 2010–March 2011). Secondary outcome measures included necrotizing enterocolitis (NEC) rates and lengths of stay. California Perinatal Quality of Care Collaborative hospitals not participating in the project served as a control population.

RESULTS: The breast milk feeding rate in the intervention sites improved from baseline (54.6%) to intervention period (61.7%; $P = .005$) with sustained improvement over 6 months postintervention (64.0%; $P = .003$). NEC rates decreased from baseline (7.0%) to intervention period (4.3%; $P = .022$) to sustainability period (2.4%; $P < .0001$). Length of stay increased during the intervention but returned to baseline levels in the sustainability period. Control hospitals had higher rates of breast milk feeding at baseline (64.2% control vs 54.6% participants, $P < .0001$), but over the course of the implementation (65.7% vs 61.7%, $P = .049$) and sustainability periods (67.7% vs 64.0%, $P = .199$), participants improved to similar rates as the control group.

CONCLUSIONS: Implementation of a breast milk/nutrition change package by an 11-site collaborative resulted in an increase in breast milk feeding and decrease in NEC that was sustained over an 18-month period. *Pediatrics* 2012;130:e1679–e1687

The benefits of breast milk are well recognized as providing health benefits in early infancy and extending into adulthood, and breast milk feeding is promoted by numerous professional organizations.^{1–9} Current research confirms that breast milk with appropriate fortification for the very low birth weight (VLBW) infant is the optimal care for both preterm and term infants.^{1,10–13} The benefits of breast milk for VLBW infants include faster stomach emptying^{14,15}; fewer gastric residuals^{16,17}; stimulated gastrointestinal growth^{18–21}; enhanced nutrient absorption²²; reduced incidence of necrotizing enterocolitis (NEC)^{23–25}; fewer episodes of bacteremia, sepsis, and urinary tract infections^{26–29}; improved visual development^{27,30,31}; and higher IQ scores.^{32–34}

Despite the evidence supporting the use of breast milk feeding in VLBW infants, a recent study of the California Perinatal Quality of Care Collaborative (CPQCC) found that only 61% of VLBW infants were discharged from the hospital on any breast milk.³⁵ While there are occasional medical contraindications to the use of a mother's breast milk, such as galactosemia, the most common reason for not providing breast milk to VLBW infants is simply a lack of availability. A mother's successful commitment to supplying her milk is likely to have significant medical benefit for her VLBW infant in both the short- and long-term.¹³

The goal of the 11-site CPQCC/California Children's Services (CCS) Breastmilk Nutrition Quality Improvement Collaborative was to improve breast milk feeding at discharge for VLBW infants by using known evidence-based practices. The primary objectives of this study were to (1) evaluate the effect of the collaborative on breast milk feeding rates in VLBW infants over the course of the 12-month project and (2) determine the sustainability of any improvements at the end of a subsequent 6-month

sustainability phase. Our hypothesis was that the collaborative project would result in an increase in breast milk provision rates for premature infants at participating sites from baseline to the intervention and sustainability periods.

METHODS

Study Population: NICUs

Eleven NICUs in CPQCC participated in a 12-month quality improvement collaborative initiative entitled The CPQCC/CCS Breastmilk Nutrition Quality Improvement Collaborative. Inclusion criteria required membership in CPQCC and participation for the entire project period. This project was sponsored by CPQCC (Stanford, CA), a consortium of 129 NICUs in California accounting for 7000 admissions and >90% of all VLBW births in California in 2009.³⁶ CPQCC is a data-driven quality improvement organization that collects standardized data and provides benchmarks and site-specific data reports; it also conducts various performance improvement activities.^{36,37} This project was open to all 129 NICUs affiliated within CPQCC as of September 30, 2009, and was funded by the participating NICUs and subsidized by CPQCC Research and Development funds. An e-mail invitation was sent to all CPQCC site contacts with their breast milk feeding rates, the state interquartile range, a statement of cost, and a request to respond with participation based on a first-come, first-served basis. Each participating site obtained local institutional review board approval or waiver to participate. We consulted the SQUIRE guidelines in the formulation of this report.³⁸

The CPQCC membership that did not participate in the collaborative project served as a natural control group to compare trends over time. Because all participants in the quality improvement collaborative were regional (Level III C/D) and community (Level III A/B) hospitals,³⁹ only regional and community Level III

hospitals were considered for the control group. The participant and control groups represent all of the designated regional and community NICUs in the state.

Study Population: Patients

Subjects were eligible for inclusion if they were 401 to 1500 g at birth, or 22 to 29 weeks' gestational age, admitted between October 1, 2008, and March 31, 2011, either inborn, or an outborn transferred into a CPQCC NICU within 48 hours of birth, and either discharged from the hospital or transferred to another CPQCC hospital for the purposes of growing or discharge. Subjects were selected and classified based on admission date, regardless of date of discharge. The analytic cohort represents a complete census of eligible patients from study NICUs.

Intervention

The project design and content were developed by a multidisciplinary expert panel consisting of 6 external subject matter experts (3 neonatologists, 1 registered dietician, 1 lactation expert, and 1 NICU nurse, each with extensive breast milk feeding expertise), 2 improvement/process experts, and 1 project manager. This expert panel developed a comprehensive, VLBW-specific "change package" of evidence-based practices distilled from extensive literature review. This change package (available at www.cpqcc.org) was based largely on the toolkit "Nutritional Support of the Very Low Birth Weight Infant Quality Improvement Toolkit" previously developed by CPQCC and updated before the start of the collaborative.⁴⁰

Because the change package was broad in scope, 3 primary intervention categories were selected for active collaboration: providing education and advocacy for the provision of breast milk, establishing and maintaining an appropriate maternal milk supply, and establishing a

TABLE 1 Change Package for the CPQCC/GCS Breastmilk Nutrition Quality Improvement Collaborative

Strongly Recommended (Initiate First)	
1. Educate/advocate for human milk for NICU (all) infants Appropriate knowledge/skills/attitudes for providers	Examples: <ul style="list-style-type: none"> • Give current evidence-based information • More consistent information to parents • Orientation of new staff includes education about breast milk feeding and hospital protocols
Appropriate education for mothers and families	Examples: <ul style="list-style-type: none"> • Breast milk as medicine, not just nutrition • Risks of not receiving human milk • Special needs of preterm and ill infants
Hospital policies and procedures to support breast milk feeding	Examples: <ul style="list-style-type: none"> • Breast milk collection and storage • Breastfeeding support
Establish access to, and use of, donor milk	
2. Establish and maintain maternal milk supply Contact with infant	Examples: <ul style="list-style-type: none"> • Holding infant • Support pumping at bedside to limit separation
Nonpharmacologic milk stimulation/massage and manual expression	Examples: <ul style="list-style-type: none"> • Breast massage and hand expression • Early, frequent milk expression
Early use of expressed milk	Examples: <ul style="list-style-type: none"> • Mouth care with small volumes of milk expressed in the early days of pumping • Begin trophic feeds early (hours to days of life rather than days to weeks) as medically able
Galactagogue use	Examples: <ul style="list-style-type: none"> • Use galactagogues safely and appropriately to increase milk supply. • Decide who will assess mothers for contraindications and risk factors
Monitoring milk supply	Example: <ul style="list-style-type: none"> • Educate parents importance of initiating early milk expression process • Pumping log or diary • Ask mother questions at strategic times – “How is pumping going?” • Note quantity of milk brought in and make appropriate referrals if below recommended amounts
Lactation experts	Examples: <ul style="list-style-type: none"> • Serve as resource for mothers and families, nursing staff, and medical providers regarding lactation issues • Facilitate optimal support measures for realizing institution stated goals of optimal milk supply and breastfeeding
3. Establish consistent comprehensive nutritional monitoring	Examples: <ul style="list-style-type: none"> • Define roles for how different participants are expected to support patient's nutritional documentation • Create either more user-friendly paper or electronic formatted nutritional snapshot for each patient
Recommended (initiate when above completed)	
1. Standardized feeding management Standard definition feeding intolerance Feeding advancement for optimal growth, including optimal fortification	
2. Use methods to support transition to breastfeeding Skin-to-skin care Non-nutritive breastfeeding Test weighing Alternative feeding methods	

consistent and comprehensive nutritional monitoring program (Table 1).

The Institute for Healthcare Improvement Collaborative Quality Improvement model was used for this project.⁴¹ Critical components of this model, all of which

were used to facilitate quality improvement in this collaborative, included the model-based meeting structure (learning sessions), supportive communication structures (monthly conference calls, active listservs, and ready access

to an expert panel including quality improvement experts), availability of best practice information (change package, slide decks, and webcast recordings), and required transparent monthly data submission and reporting. Each site

assembled a multidisciplinary team including at a minimum a physician lead, a nurse lead, a designated site leader, and an administrative leader. Hospitals learned improvement methods and strategies based on the Institute for Healthcare Improvement Model for Improvement.⁴² During the 12-month intervention phase, site teams made numerous process improvements and reported key outcome and process measures monthly into a secure Web-based repository, which were reported on a monthly basis along with trends over time. Continued data collection and entry were recommended, but not required, during a 6-month sustainability phase. Full transparency, including unblinded data and open sharing of successes and barriers, was required for participation. The effort was coordinated by a project manager employed by CPQCC. Expert panel members provided feedback to sites, planned and implemented 3 learning sessions, provided content oversight and process management for the collaborative, communicated progress to site-specified leaders on an ongoing basis, and produced final deliverables describing the results of the project.

We considered 3 periods for comparison: baseline phase of 12 months (infants born between October 1, 2008, and September 30, 2009), the implementation phase of the project that spanned 12 months (infants born between October 1, 2009, and September 30, 2010), and a sustainability phase of 6 months (infants born between October 1, 2010, and March 31, 2011). Data collection continued until final disposition or until June 30, 2011, whichever came first. An annotated run chart similar to the monthly data presentations given to collaborative participants was constructed for the primary outcome measure of breast milk feeding at discharge from the hospital.

Outcome Measures

The primary outcome measure was the percentage of eligible VLBW infants

discharged from the hospital on any breast milk. Secondary metrics included (1) incidence of NEC and (2) average length of stay for eligible infants. Although each site contributed data to an extranet for the purposes of the collaborative project and to track processes along with other participants, the data analysis for this study used the existing CPQCC data set. CPQCC member hospitals, including both participants and the controls, participate in a standardized data collection. All metrics evaluated in this study are included in this standardized data collection, including those used for risk adjustment. Annual training sessions conducted by CPQCC promote accuracy and uniformity in data abstraction. Each record has range and logic checks at the time of both data collection and data closeout, with auditing of records with excessive missing data.

Statistical Methods

The null hypothesis was that there would not be any change in VLBW breast milk feeding rates over time. The percentage eligible infants discharged from the hospital on any breast milk, percentage eligible infants developing NEC, and eligible infant mean length of stay were compared by using χ^2 test or Student's *t* test. Time periods were categorized as baseline period (12 months before intervention), intervention period (12 months during intervention), and for comparisons.

As the patient and hospital characteristics may have been different for participants and the control group, we used a random-effects logistic regression model to account for potential confounding factors including socio-demographic and medical factors, including birth weight. Risk adjustment variables were those found to be relevant to the outcomes of interest from previous studies and those used currently in the risk adjustment used by CPQCC for

benchmarking.^{35,36} The main predictor variable of interest was time period, with estimation of odds ratios and 95% confidence intervals. Records with missing data were not incorporated into models (1% of records). Analyses were performed by using SAS 9.1 (SAS Institute, Inc, Cary, NC).

Practice Survey

In the last month of the collaborative, an electronic survey was administered to the site project leaders. Participants were asked which key practices had already been in place before the collaborative and which had been adopted during the course of the intervention period.

RESULTS

Eleven NICUs participated in the collaborative and 88 CPQCC NICUs that did not participate formed the control population (Table 2). All 11 collaborative NICUs remained actively involved during the 18-month implementation and sustainability phases.

Baseline breast milk feeding rates were significantly higher in the control group (64.2%, SD 47.9%) compared with collaborative participants (54.6%, SD 49.8%). After intervention, the percentage of eligible collaborative VLBW infants discharged from the hospital on any breast milk increased from baseline to implementation phase (mean 61.7%, SD 48.6%; $P = .005$) with continued improvement during the sustainability phase (64.0%, SD 48.1%; $P = .003$, Table 3 and Fig 1). Compared with baseline, 9 hospitals had increased breast milk feeding rates in the intervention and sustainability periods combined, while 2 hospitals decreased.

For collaborative participants, mean NEC rates decreased during the implementation phase (7.0%–4.3%, $P = .02$) with continued decrease during the sustainability phase (2.4%; $P < .0001$). Compared with

TABLE 2 Characteristics of Participant and Control NICUs

	Participants	Control Group	<i>P</i> ^a
Hospital characteristics			
<i>N</i>	11	88	
Level of care, No.			
Regional (III C/D)	5	18	.06
Community (III A/B)	6	70	
Median NICU VLBW volume for study period, No.	214	108	.11
Patient characteristics			
<i>N</i>	1833	7380	
Prenatal care, %	96.9	97.3	.40
Mean maternal age, y	28.1	29.4	<.0001
Maternal race, %			
Black	18.9	11.6	.0001
White	53.6	51.3	
Asian/Pacific Islander	11.5	11.8	
Native American	0.7	0.6	
Other	14.6	24.1	
Unknown	0.7	0.7	
Ethnicity			
Hispanic, %	38.6	46.8	<.0001

^a *P* value for *t* test or χ^2 test.

baseline, 8 hospitals had decreased NEC rates in the intervention and sustainability periods combined, 2 hospitals increased, and 1 hospital remained the same. Mean lengths of stay increased between baseline and implementation phases but returned to baseline levels during the sustainability phase (Table 3). In the control sites, the percent eligible infants discharged from the hospital on any breast milk did not change from baseline period to intervention period but did increase during the sustainability

period to 67.7% (Table 3). NEC rates were lower at baseline (3.6%) compared with collaborative participants and decreased to 2.1% during the sustainability period (*P* = .004, Fig 2). Length of stay was similar in the control group for all 3 periods (Table 3 and Fig 3). While breast milk feeding rates were significantly lower in the collaborative participants compared with the control group at baseline, this difference disappeared during the implementation and sustainability periods. NEC rates were also significantly

higher for collaborative participants at baseline compared with controls but were not different than controls during the intervention or sustainability periods.

In multivariable analyses adjusting for sociodemographic and medical risk factors, there was a 44% increase in odds of breast milk feeding at discharge for participants during the sustainability phase compared with baseline, compared with a 15% increase for the control group (Table 4). NEC rates were significantly lower during both the intervention and sustainability periods compared with baseline for participant hospitals.

At the end of the collaborative project, a survey was administered asking which of the key recommended practices had been adopted before or during the course of the project. All participants responded. By the end of the intervention period, most key recommended processes had been adopted by the majority of participants (Fig 4).

DISCUSSION

The goal of the CPQCC/CCS Breastmilk Nutrition Quality Improvement Collaborative was to increase breast milk feeding in VLBW infants in 11 participating hospitals. Breast milk feeding rates improved significantly from 54.6% to 61.7% between baseline and implementation periods, with continued increases during a 6-month sustainability phase to 64.0%. NEC rates decreased significantly from baseline (7.0%) to implementation (4.3%) to sustainability phases (2.4%). While other quality improvement projects related to breast milk and nutrition have been demonstrated for the general newborn and preterm populations,^{43–46} we believe this to be the first report of a collaborative quality improvement initiative demonstrating a significant and sustained increase in breast milk feeding rates at discharge

TABLE 3 Baseline, Intervention, and Sustainability Period Outcomes for Collaborative Sites (*n* = 11) and Control Sites (*n* = 88)

	Baseline Period (October 1, 2008–September 30, 2009)	Intervention Period (October 1, 2009–September 30, 2010)	Sustainability Period (October 1, 2010–March 31, 2011)
<i>N</i>			
Participants	797	697	339
Control group	3020	2903	1457
Breast milk at discharge			
Participants, %	54.6	61.7*	64.0*
Control group, %	64.2	65.7	67.7*
NEC			
Participants, %	7.0	4.3*	2.4*
Control group, %	3.6	2.7	2.1*
Length of stay, mean d			
Participants	67.5	71.3*	66.8
Control group	61.4	62.1	62.5

The number of records missing outcome variables were breast milk at discharge, *n* = 1; NEC, *n* = 5; and length of stay, *n* = 1.

* *P* < .05 for comparison against baseline period.

FIGURE 1
Annotated run chart of breast milk feeding at discharge for collaborative participants.

for VLBW infants accompanied by a decrease in the incidence of NEC.

Although this was a longitudinal evaluation of a quality improvement project performed at 11 hospitals, we were able to have a comparison group because data on outcomes were collected in the same way for other California NICUs, providing a sense of secular trends. This control population did not significantly change between baseline and intervention periods but did have an increase during the sustainability time period: an increase from 64.2% to 67.7% over this 2½-year period. It is notable

that the participant hospitals started at a significantly lower baseline rate of 54.6%. Although an invitation was sent to all CPQCC hospitals, it appeared that the NICUs that joined were appropriate to participate in a project to improve breast milk nutrition. Additionally, NEC rates were significantly higher at baseline for participant hospitals, but were able to achieve similar rates as nonparticipants by the sustainability period, decreasing from 7.0% to 2.4%. Although we analyzed outcomes by 3 discrete time periods, participants may have started some preliminary work

before the intervention period. On the other hand, the ramp-up during the initial part of the intervention period may have not been immediate. Either of these scenarios would have attenuated the differences found between the baseline and intervention periods.

Based on these results, we believe that important reductions in morbidity and health care costs are possible if our change package to increase breast milk feeding were further disseminated. If there were 4000 VLBW infants in California per year with a breast milk feeding rate of 61%, a relative increase of 25% for this population would translate to an increase to above 75%, a potentially significant public health impact. As health care costs continue to rise at unsustainable rates in the United States, opportunities for safe and cost-effective solutions such as these will be increasingly important to identify.

A unique and interesting aspect of this collaborative was what was freely shared among the sites and the expert panel, whose affiliated hospitals were not collaborative participants. Policies and procedures, which can be time

FIGURE 2
Percent of eligible infants with NEC by collaborative participation.

TABLE 4 Multivariable Analyses for Breast Milk Feeding at Discharge and NEC

Time Period	Breast Milk Feeding at Discharge ^a		NEC ^a	
	Participants	Control	Participants	Control
Baseline (October 1, 2008 –September 30, 2009)	Reference	Reference	Reference	Reference
Intervention (October 1, 2009 –September 30, 2010)	1.31 (1.05–1.64)*	1.03 (0.92–1.16)	0.59 (0.37–0.94)*	0.78 (0.58–1.06)
Sustainability (October 1, 2010 –March 31, 2011)	1.44 (1.09–1.91)*	1.15 (0.99–1.33)	0.36 (0.17–0.76)*	0.61 (0.40–0.92)*

^a Odds ratios are presented with 95% confidence intervals with the baseline period as the reference. Risk adjustment variables for the breast milk feeding model included maternal age, prenatal care, outborn status, surgery, birth weight, race/ethnicity, and oxygen use at 36 wk. Risk adjustment variables for the NEC model included NICU level, gestational age, and race/ethnicity.

* $P < .05$.

consuming to write and implement, are not commonly shared between hospitals. However, the collaborative group freely shared such policies and procedures, such as skin-to-skin contact, use of donor breast milk in the NICU, and oral colostrum care. This was especially helpful because of the tight time line of the collaborative. The group also shared parent brochures, transport letters (including a Spanish translation), and staff education materials. The attitude was genuinely generous and supportive among sites.

This study had several limitations. First, we did not formally evaluate compliance with individual elements of the change package. Our goal was to maximally improve breast milk feeding rates in VLBW newborns by implementation of change package components most relevant to individual sites, rather than stressing compliance to specific components. This potentially limits our

ability to directly link the intervention with the outcome. Although each site in the collaborative entered monthly compliance rates to each component of the change package into the database, these data were not audited. These compliance data were collected for quality improvement purposes and not for proving causality or for measuring actual changes made; more rigorous collection and submission of compliance to elements in the change package were beyond the scope of this pragmatic quality improvement project. However, these data were tracked on a collaborative-wide basis and individually during the intervention period, and participants acknowledged general adoption of key recommended practices (Fig 4).

Second, the pre-post intervention study design limits our ability to assign causality between the intervention and the primary outcome of breast milk feeding at discharge, as well as the secondary

outcome of NEC. Evidence supporting that this improvement is related to change package implementation is reflected in the lack of improvement in breast milk feeding rates in control sites during the intervention phase. In pre-post studies, it is challenging to determine the effect of secular trends on outcomes; however, it would be unlikely that any confounding interventions would have only affected the intervention NICUs without affecting our control population. The availability of a large and diverse control population with reliable comparison data, including variables used in risk adjustment, adds credibility to our assertion of an association between change package implementation and increased breast milk feeding rates. Nevertheless, this was also not a perfect control group, as provision of human milk for premature infants was a prominent topic during state meetings, in which the control group could have been exposed to the best practices used in the collaborative project. Furthermore, the toolkit was and is freely available to anyone, even those who are not members of CPQCC.

Finally, the 11 participants in this collaborative were collectively underperforming in breast milk feeding rates compared with the control population at the start of the collaborative. The invitation to participate included each site's rate along with state benchmarks. It is natural that sites struggling to establish breast milk feeding rates comparable to their peers would be attracted to a collaborative promising improvement. It is conceivable that the

FIGURE 3

Mean length of stay for eligible infants by collaborative participation.

FIGURE 4
Percent of processes adopted by collaborative participants before and during the intervention.

magnitude of improvement resulting from participation was exaggerated as a result of the intervention being implemented in below-average performers. The ability to increase breastfeeding rates may depend on the need and interest of the NICU to improve.

CONCLUSIONS

Coincident with implementation of an expert panel constructed change package, we saw an increase in breast milk feeding rates in an 11-site improvement collaborative from 54.6% to

61.7% over a 12-month time frame, with incremental improvement to 64.0% over the subsequent 6-month post-collaborative period, with a concomitant lowering of NEC rates. Broad use of these best practices could significantly reduce morbidity and costs of health care.

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