The Standard in Newborn Nutrition; Building a Non-profit Milk Bank

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UC San Diego Health
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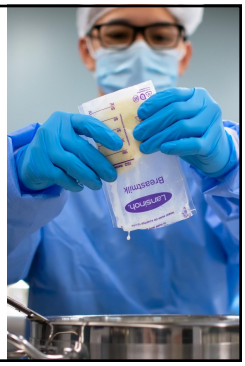
UNIVERSITY OF CALIFORNIA HEALTH Milk Bank



Building a Non-Profit Milk Bank

- Regional needs
- Timeline
- Gathering data and support
- Regulatory preparation
- Building the facility
- Operations planning
- Hospital sales
- Marketing

Regional Need

- What non-profit and commercial milk banks provide milk in your region?
- Who is supplying your level 3 and 4 NICUs?
- Are they meeting the need?
- How much milk do they use?
- Are donors in your region engaged?
- Are there milk depots in your region set up by other milk banks?
- Will you be in competition with others?
- Will you have a market for families at home?
- What are the insurance coverage issues in your state?

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 71 / No. 31 August 14, 2022

Donor Human Milk Use in Advanced Neonatal Care Units — United States, 2020

Allison E. Bennett, MS[1]; Anna M. Lessen, PhD[2]; Jennifer M. Nelson, MD[1]

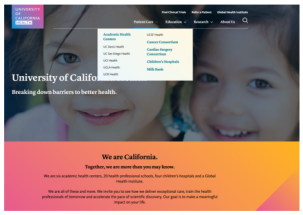
Approximately 50,000 infants are born in the United States each year with very low birthweight (VLBW) (<1,500 g) and are at high risk for morbidity and mortality that include decreased risk for necrotizing enterocolitis, a serious illness resulting from inflammation and death of intestinal tissue, and improved neurodevelopmental outcomes in short-term and long-term follow-up for those who are fed human milk but consumed formula instead (1–3). Human milk is also associated with improved clinical outcomes in preterm infants and is unavailable or insufficient, potential donor human milk is screened for infectious diseases, and pasteurized donor human milk is an essential alternative for infants with VLBW (4). CDC's 2020 Maternity Practices in Infant Nutrition and Care (mPINC) survey found that 1,000 of 1,000 (100%) of the 1,000 U.S. advanced neonatal care units (ANCUs) that provide care to infants ≤32 weeks gestational age (GA) reported that they provide human milk to infants with VLBW (5). Among 1,000 hospitals with ANCUs, 1,000 (100%) reported that human milk was available for infants with VLBW; however, approximately one half (54.7%) reported that more (>50%) infants received human milk from a donor than received human milk for infants with VLBW (or more commonly reported among hospitals with a level IV unit, higher annual birth volume, and teaching status). Hospitals with higher annual birth volume and teaching status, and those designated Baby-Friendly Hospitals (6) were more likely to report that donor human milk helps reduce that infants with VLBW receive donor milk when mother's own milk is unavailable and reducing infant morbidity and mortality in infants with VLBW.

The mPINC survey is a biennial census of all maternity care hospitals in the United States and territories to monitor progress in implementing 41 evidence-based practices (7). Data are completed electronically by the primary care knowledgeable about the hospital practices related to infant nutrition. In 2020, 1,000 (100%) of 1,000 hospitals with ANCUs responded to an EHR-based survey (infants ≤32 weeks gestational age [GA] and ≤1,500 g birthweight [BW]). Among 1,000 (100%) of 1,000 hospitals (100%) cases (100%–100%), many (50%–70%), some (10%–49%), and few (<10%) of cases with donor milk available.

Data on donor human milk use were examined by sociodemographic characteristics, including GA, BW, and sex, for infants weighing ≤1,500 g, analyses included hospitals with level II, III, or IV units.

MMWR series publication information, see www.cdc.gov/mmwr and https://stacks.cdc.gov/browse/series/MMWR
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

UNIVERSITY OF CALIFORNIA HEALTH Milk Bank



- Launched with philanthropic gift
- Owned and operated by the University of California, San Diego, Health
- Located at the San Diego Blood Bank
- Accredited in Sept 2020
- First milk bank led by a physician
- We were the 30th non-profit milk bank in North America
- The first non-profit HMBANA milk bank in Southern California
- First milk bank owned by a hospital system
- UC Health is the largest academic medical center system in the US

University of California Health Milk Bank Timeline

Johnson Family Gift, 2016

Construction, Spring 2020

Team Hired, June 2020

Opening, Sept. 2020!

Project Approval, August 2019

UC Health Co-Branding, May 2020

UNIVERSITY OF CALIFORNIA HEALTH Milk Bank

CSM Go Live, August 2020

Milk Bank Development Timeline

Cultivating an Innovative Environment

*Before the physicians at UC San Diego Health Pediatrics could even begin to conceptualize a hospital owned and operated facility, it needed to **create an environment** that was condusive to innovative programs and attract potential donors.*

spin — SUPPORTING PREMATURE INFANT NUTRITION

Baby-Friendly USA

01 Cultivating
02 External Setbacks
03 Internal Setbacks
04 Revitalization
05 Operationalize

Cultivating an Innovative Enviroment

2006	UCSDH certified as a Baby Friendly Hospital
2008	UCSD develops the SPIN Program
2009	After participating in donor milk study, UCSD begins use of PDHM
2010	Drs. Kim and Stellwagen conceive of starting a regional milk bank
2013	March of Dimes milk bank application- not awarded
2015Dec	Hannah Johnson gives $1000 to Mothers Milk Fund
2016Jan-June	Discussions with the Johnson Family regarding gift
2016July	Johnson Family gives $1,000,000 gift to launch the Milk Bank

Milk Bank Development Timeline

External Setbacks: Competitor Obstacles and Developing Milk Bank Status Delay

*Though the initial $1,000,000 gift made the milk bank a possibility, **external competitors** blocking development resulted in delays and inefficient use of the initial gift. The Milk Bank founders **took the initiative to find other supports and routes to success.***

MOTHERS' MILK BANK

01 Cultivating
02 External Setbacks
03 Internal Setbacks
04 Revitalization
05 Operationalize

External Setbacks: Competitor Obstacles and Accreditation Delay

2017 All year	Initial mentor, in-person kick off meeting, 3 milk drives
2017 June	HMBANA application
2017 Nov	Legal struggles
2018 Feb	SBAR approval- Milk Bank to be run out of Pediatrics
2018 April	New HMBANA CEO helps restart our application
2018 May	MMB Austin agrees to mentor us
2018 May	IMC presentation 1st step
2018 June	HMBANA grants developing milk bank status
2018 July-Dec	Business plan drafted, CEO approves in Dec.
2018	Johnson Family considers second gift for milk bank construction/operation

Milk Bank Development Timeline

Internal Setbacks: Disapproval and Project Pause

*With the mentorship of Austin MMB and growing support from the community, the Milk Bank was on track to open on an expedited timeline. However, UCSDH determined the Milk Bank would have no Health System financial support, **halting the project**. The team needed to **revise the budget and garner additional community support.***

UC San Diego Health — INITIATIVE MANAGEMENT COMMITTEE DO IT

01 Cultivating
02 External Setbacks
03 Internal Setbacks
04 Revitalization
05 Operationalize

Internal Setbacks: Disapproval and Project Pause

2019 Jan	Gift for milk analyzer
2019 Jan	Anonymous gift 35K
2019 Jan	IMC presentation
2019 Feb	Discussion institutional support with Chancellor and UCSDH CEO
2019 Feb	Draft equipment and IT needs
2019 Mar	SDBB architect and construction plans commence
2019 Apr	CEO says no go without more funds
2019 Apr	KW family gift 19K
2019 Apr	Project put on hold

Milk Bank Development Timeline

Revitalization: Community and Institutional Support

*After seeking other avenues of financial support, SD County Supervisors collectively granted $400k for development. With additional **community support and a revised budget, the project was restarted and enthusiastically supported.** The Health System found other ways to support development, including dedicating more UCSDH staff to the team and advocating co-branding to UC Health.*

UNIVERSITY OF CALIFORNIA HEALTH Milk Bank

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Revitalization: Community and Institutional Support

2019 May	Supervisor Gaspar grant 95K for equipment
2019 May-Aug	Redrafting proforma scaling down equipment/staff; CFO approval of proforma
2019 Aug	IMC presentation of balanced proforma- CEO approves and moves Milk Bank to Health
2019 Sept	Johnson Family gives $4 M gift
2019 Oct	Failed seismic assessment; SDBB fails UC required inspection
2019 Nov	Find waiver for seismic assessment; SDBB contract commences, completed 3 months later
2019 Nov	Grants from County Supervisors total 300K (Gaspar, Fletcher, Cox, Desmond)
2019 Nov	Dr. Steilwagen completes mini-MBA program
2019 Dec	City approves building plans
2019 Dec	Anonymous gift 35K
2019 Dec-Jan	Discussion with CEO about UC Health name, Executive VP of UC Health approves of name
2020 Jan	Equipment and IT list finalized

Milk Bank Development Timeline

Operationalize

*Following four years of Milk Bank development, and 14 years of overall program development, the team had a short seven months to **turn a business plan into an accredited program and facility.** Due to thorough planning and unwaivering dedication, the UC Health Milk Bank successfully opened in August.*

01 Cultivating
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03 Internal Setbacks
04 Revitalization
05 Operationalize

Operationalize

2020 Feb	Begin HR process for 5 hires
2020 Feb	Construction and escrow agreements signed
2020 Feb	Construction begins and finishes in 91 days right on time (during pandemic!)
2020 April	5 staff hired
2020 May	Facility opens and equipment fit-up
2020 June	New staff start
2020 June - Oct	Present and negotiate service agreement (SA) proposal to SDBB
2020 Aug	HMBANA accreditation as 30th milk bank in NA (3 months after move in)
2020 Sept	First milk sale
2020 Oct.	Agreement on SA with SDBB

Gathering Data And Support

- Assemble a team
- Executive Director choice
- Community/regional needs assessment
- Fund raising
- Budget construction
- Institutional support
- Regulatory
- Milk Bank board/medical advisors

Patty Maysent, CEO UCSD Health

Medical Advisory Board

Christopher Longhurst, MD, MS
- Chief Medical Officer and Chief Digital Officer, UCSDH

Christina Chambers PhD, MPH
- Professor, Division of Dysmorphology and Teratology, Pediatrics, UCSD SOM
- Program Director, Mommy's Milk Human Milk Research Biorepository

Philip O. Anderson Pharm.D., FASHP, FCSHP
- Clinical Professor, Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, UCSD
- Founder and Principal Author, LactMed®

Lars Bode, PhD
- Professor, Pediatrics, UCSD SOM
- Center Director, LRF MoMI CoRE

Michelle Leff, MD
- Associate Professor, Pediatrics, UCSD SOM
- Newborn Hospitalist, UCSD

Elizabeth Mannino Avila, MD
- Assistant Professor, Pediatrics, UCSD SOM
- Pediatric Hospitalist, Rady CHSD

Katherine Weiss, MD
- Assistant Professor, Pediatrics, UCSD SOM
- Neonatologist, Rady CHSD

Jae H. Kim MD, PhD
- Professor, Pediatrics
- Division Chief, Neonatology, Cincinnati Children's Hospital

Christine Bixby, MD
- Clinical Associate Professor of Pediatrics, UCI SOM
- Neonatologist, Children's Hospital of Orange County

Mark H. Sawyer, MD
- Professor, Clinical Pediatrics, UCSD SOM
- Program Director, UCSD/Rady Children's Hospital San Diego Pediatrics Residency

Kim Speckhahn BS, IBCLC
- Lactation Consultant and Regional Breastfeeding Liaison, WIC, North County Health Services

Carrie Byington MD (ex-officio)
- Executive Vice President, UC Health

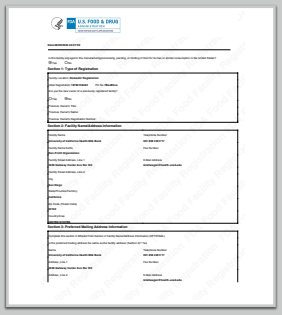
Philanthropy

- Johnson gift funds development and second gift funds construction and operations
- Additional anonymous gifts
- SD County Supervisors gave $580K
- 18K Gift for bereavement program
- 50K Gift for bridge milk program

Hannah and Zachary Johnson

Regulatory Preparation

- HMBANA membership
- FDA food facility registration
- Regional regulations
  - Local food operations rules
  - Water safety report
  - Public health regulations
- Institutional rules



U.S. FOOD & DRUG ADMINISTRATION

Section 1: Type of Registration

Section 2: Facility Name/Address Information

Section 3: Preferred Mailing Address Information

Budget Preparation

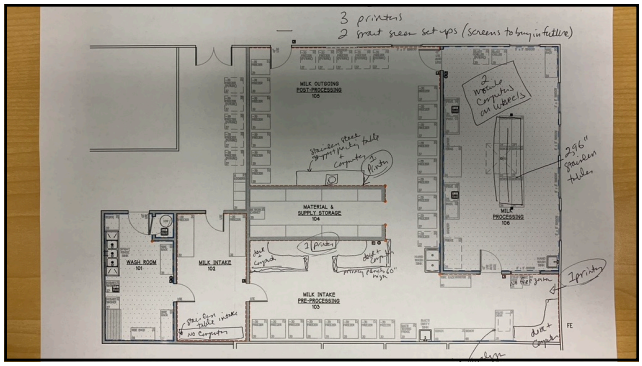
	Notes		Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
Volume[1]								
Donors			10,000	12,500	15,625	19,531	24,414	82,070
Ounces Collected		250	2,500,000	3,125,000	3,906,250	4,882,813	6,103,516	20,517,578
Ounces ordered[2]			30,000	120,000	180,000	240,000	300,000	870,000
Revenue[3]								
Orders[4]	$	4.63	139,500	558,000	837,000	1,116,000	1,395,000	4,045,500
Medical Write-Off	20% of total sales		27,900	111,600	167,400	223,200	279,000	-
Gifts/Donations								-
Remaining Gift Amount			200,000	100,000				300,000
Additional Fundraising[5]			10,000	20,000	30,000	40,000	50,000	150,000
Total Revenue			321,600	669,600	1,004,400	1,339,200	1,674,000	5,008,800
Expenses								
SDBB Lease (2,500 sqft)[6]	$2.80/sqft/mo		84,000	84,000	84,000	84,000	84,000	420,000
Utilities								-
SDBB FTEs (Year 1 only)	1 FTE collections. 1 FTE shipping		$ -	$ -	$ -	$ -	-	-
Service Fees								-
Consumable supplies								-
Parking Spaces at SDBB	4 spaces year 1, 6 spaces subsequent years							-
Shipping	$50/site/day							-
Delivery Ref	$50/delivery							-
Facility Buildout Costs[7]	$	250,000	250,000					250,000
Tissue Bank Storage	$3,000/year		1,000	1,000	1,000	1,000	1,000	5,000
Equipment & Supplies			492,550	115,800	126,000	138,100	151,410	1,023,860
Equipment Maintenance								-
Equipment Overhead								-
Milk Bank App Software[8]	$	150,000	150,000	-	-	-	-	150,000
Timelaxa Medical Software			18,000	18,000	18,000	18,000	18,000	180,000
FedEx Shipping Fees	$	0.40	12,000	48,000	72,000	96,000	120,000	348,000
Donor Blood testing[9]	$	0.50	5,000	6,250	7,813	9,766	12,207	41,035
Donor Screenings	$	1.00	10,000	12,500	15,625	19,531	24,414	82,070
Marketing	$	30,000	50,000	50,000	50,000	50,000	50,000	250,000
Board Meetings & Conferences	$20,000/year		20,000	20,000	20,000	20,000	20,000	100,000
Unfunded research on milk quality	$20,000/year		20,000	20,000	20,000	20,000	20,000	100,000
Training for staff	One time $20,000		20,000					-
Mobile App	$	30,000	30,000	30,000	30,000	30,000	30,000	150,000
Misc			30,000	6,000	6,000	6,000	6,000 [illegible]	-

Building The Facility

- Facility site and plans
- Staffing
- IT needs
- Operations planning
- Equipment
- Fitting up
- Team to help you get there!

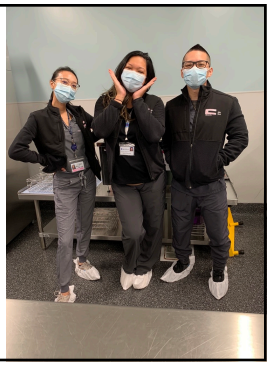
Facility Specifications

- Size (UCHMB is 3,000 SF)
- Location
- HMBANA regs
- FDA food facility regs
- Local public health/hospital regs
- Milk lab/clean room
- Cold storage decision
- Power
- Plumbing
- IT
- Generator power
- HVAC/air filtration
- Water quality
- Noise issues
- Future growth
- Community/philanthropy visits



Staff

- Leadership decision (Executive and Medical Directors)
- Job descriptions
- Hiring
- Training
- Competency assessment
- Food Safety staff certification
- Donor coordinator staff (high EQ)
- Medical Provider must sign off donor approvals
- Milk lab staff (DTR with NICU experience)
- Staff engagement and retention



Information Technology

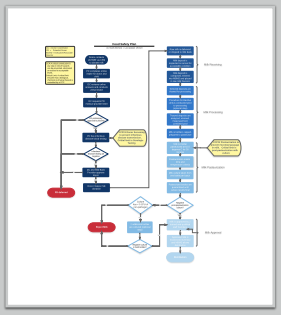
- Data tracking
- Customer engagement
- ✓CSM
- ✓Electronic Milk Bank Management System
- Shared drive for staff/SOP access
- Hospital IT systems for other functions
- Secondary cold storage thermal tracking

Operations Planning

- Leadership
- Forms & etc.
- Milk volume
- Donor screening process
- Milk Processing
- Equipment and disposables
- IT
- Microbiology
- Procurement and supply chain
- Logistics

Forms & Etc.

- Standard operating procedures for each key process
- Food safety plan
- Consent forms
- Sanitation check lists
- Training check lists and certificates
- Equipment maintenance
- Thermometer calibration
- Milk processing form

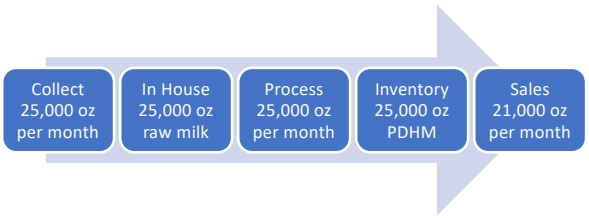


Milk Collection and Sales Drive Operational Costs

- Project regional need for PDHM
- How much milk do you need to collect?
- How much milk will be lost in processing?
- Can you work with research community if milk cannot be used?
- How much milk will you have on hand?
- What are your processing fees?
- How much milk can you sell?

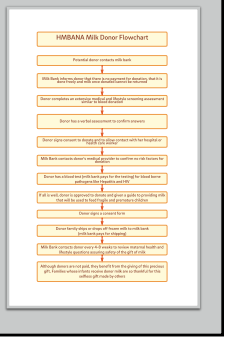
How Much Milk Will You Need To Collect?

How Much Milk Will You Have On Hand?



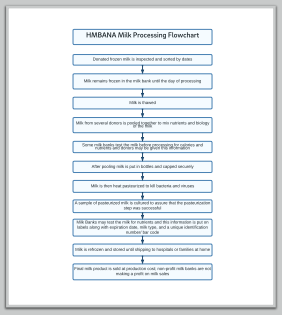
Donor Screening

- Donor coordinator
- Format for screening
- Consent forms
- Verbal interview
- Interpreter needs in your region
- Maternal medical provider form/Care Everywhere option
- Blood testing; cost, site and resulting
- Approval process (by 2 staffers)
- Tracking progress/documentation
- Retention of records
- Milk transport to milk bank



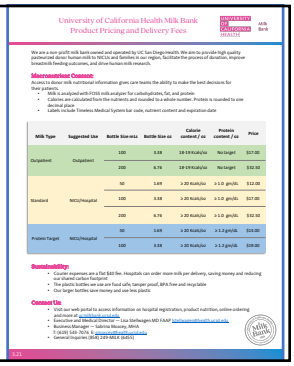
Milk processing

- Tracking milk
- Thawing
- Screening for Bacillus
- Pooling
- Mixing/dispensing
- Bottle and cap type
- Milk analysis
- Labeling
- Pasteurizer
- Data logger
- Thermometer calibration
- Rapid cooling
- Milk cultures
- Approval process



Milk Product Decisions

- Defining your product goals
- Type of product
- Name of product
- Bottle sizes
- Bottle and capping system
- Nutrient analysis
- Processing fee



University of California Health Milk Bank
Product Pricing and Delivery Fees

UNIVERSITY OF CALIFORNIA HEALTH Milk Bank

We are a non-profit milk bank owned and operated by UC San Diego Health. We aim to provide high quality pasteurized donor human milk to NICUs and families in our region, facilitate the process of donation, improve breastmilk feeding outcomes, and drive human milk research.

Macronutrient Content:

Access to donor milk nutritional information gives care teams the ability to make the best decisions for their patients.

- Milk is analyzed with FOSS milk analyzer for carbohydrates, fat, and protein.
- Calories are calculated from the nutrients and rounded to a whole number. Protein is rounded to one decimal place
- Labels include Timeless Medical System bar code, nutrient content and expiration date

Milk Type	Suggested Use	Bottle Size mLz	Bottle Size oz	Calorie content / oz	Protein content / oz	Price
Outpatient	Outpatient	100	3.38	19-19 Kcals/oz	No target	$17.00
		200	6.76	19-19 Kcals/oz	No target	$32.50
Standard	NICU/Hospital	50	1.69	> 20 Kcals/oz	> 1.0 gm/dL	$12.00
		100	3.38	> 20 Kcals/oz	> 1.0 gm/dL	$17.00
		200	6.76	> 20 Kcals/oz	> 1.0 gm/dL	$32.50
Protein Target	NICU/Hospital	50	1.69	> 20 Kcals/oz	> 1.2 gm/dL	$13.50
		100	3.38	> 20 Kcals/oz	> 1.2 gm/dL	$19.50

Sustainability:

- Courier expenses are a flat $40 fee. Hospitals can order more milk per delivery, saving money and reducing our shared carbon footprint
- Our bottle bottles we use are food safe, tamper proof, BPA free and recyclable
- Our larger bottles save money and use less plastic

Contact Us:

- Visit our web portal to access information on hospital registration, product nutrition, online ordering and more at: ucsdmilkbank.org/ucsdhb
- Executive Medical Director: Dr. Ray Dunbaugen MD FAAP raydunbaugen@ucsd.edu
- Operations Manager: Sabrina Mhoney, MPH
- 9 (858) 549-7674 ⅱ: sabrina-mhoney@ucsd.edu
- General Inquiries (858) 249-MILK (6455)

Milk Bank

3.21

Large Equipment

- Warewashers
- Pasteurizers
- Freezers or cold rooms
- Refrigerators
- Blast Chiller
- Milk analyzer
- Water softener/Reverse osmosis
- HEPA and air flow
- Associated workload:
  - Periodic maintenance
  - Periodic calibration
  - Repair costs
  - Back up equipment (2 of everything!)

Pasteurizer Choice

- Circulating water bath
- ACE (UK)
- Sterifeed (UK)
- All Holder pasteurization
- Future maybe different!

Small Equipment

- Milk pots
- Spoons/filters
- Mixers
- Dispenser
- Capping device
- Hot water bath
- Thermometers
- Autoclave
- Data loggers
- Scales
- Label printers
- Office equipment/computers
- & etc!

Disposables

1. Bottles and caps
2. Shipping boxes
3. PPE

- Dry ice
- Labels for milk bottles
- Shipping labels
- Syringes and tubes for milk process/culture
- Chux/wipes/plastic wrap
- Food safe cleaning products
- Bins and more bins
- Office supplies
- Forms

Milk Analysis

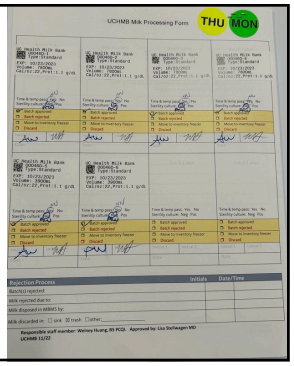
- UCHMB is nutrition/protein focused
- Most expensive equipment ($100K)
- FOSS FT1 Near IR analyzer
- 30 mLs of milk/30 seconds
- Highly accurate
- Requires periodic calibration and validation
- Very robust machine
- Analyze donor pool
- Analyze final pool
- Nutrients on label

Labeling

- Bar code
- Milk bank name
- Product name
- Expiry date
- Volume
- Macronutrients
- Marketing

Milk Bank Tracking and Management Software

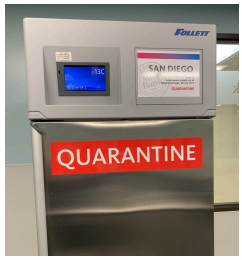
- Custom software for tracking donors and milk in a milk bank setting
- Provides framework for donor workflows:
  - Approval
  - Blood test date
  - Baby DOB
  - Exclusion dates
- Provides tracking of milk product
  - Raw milk deposits
  - Processing volumes
  - Bar coded labels
  - Milk batch approval
  - Tracking product location in milk bank
  - Tracking after sales in case of recall



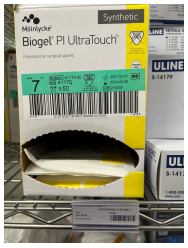
Temperature Tracking Of Cold Storage Devices

Microbiology

- Bacillus culture optional
- Post pasteurization culture mandatory
- Must be CLIA or similar certified lab
- We use UCSD Health's clinical lab
- Quarantine milk until approved
- Milk tracking software is a valuable safety step



Procurement/Supply Chain/Storage



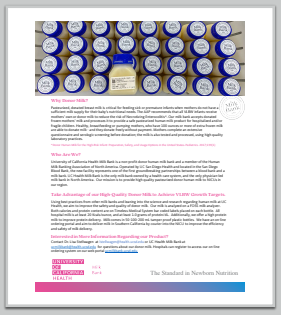
Shipping/Logistics

- Local pick up
- Courier delivery
- Milk bank delivers
- Fed Ex or UPS Shipping
- Packing and shipping materials
- Dry ice
- Cold chain documents

11/20 UCSD Medical Center Nutrition Team

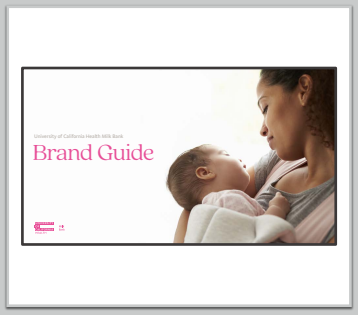
Hospital Sales

- Critical but difficult and time-consuming process
- Contacting regional hospitals
- Contracting
- Ordering
- Par level
- Shipping
- Feedback about product
- Recall/Regulatory contacts
- Developing a relationship with NICU staff
- Providing consistent, reliable service, and a product NICU can trust



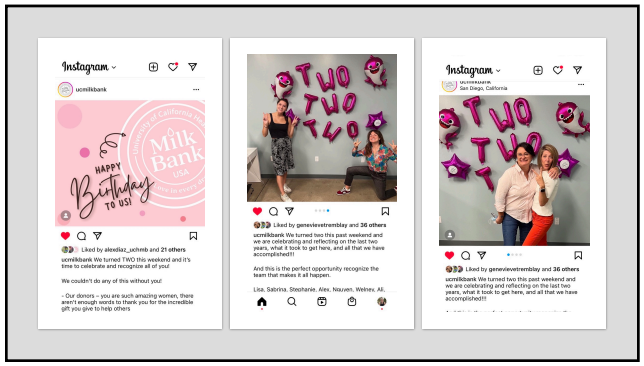
Marketing

- Targets are donors and hospitals/consumers
- Milk bank name
- Branding look
- Mission and goals
- Tag lines
- Product branding
- Important initial investment



UNIVERSITY OF CALIFORNIA HEALTH

Milk Bank

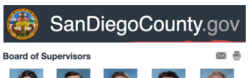


UC Health Milk Bank Lessons Learned

- Many years of preparation in your community will pay off
- Patience and perseverance
- Team leadership is key
- Adequate funding/philanthropy
- Highly organized planning
- Travel and visit other milk banks
- Start donor outreach early (during depot phase)
- Start collaboration with hospitals early
- Starting a milk bank is a priceless way to improve community health and to improve breastfeeding messaging in your region

Thank you to our generous supporters!

The Johnson Family



Genevieve Jacobs

References

1. Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States. COMMITTEE ON NUTRITION, SECTION ON BREASTFEEDING, COMMITTEE ON FETUS AND NEWBORN. Pediatrics Jan 2017, 139 (1) e20163440
2. Meek JY, Noble L. Breastfeeding and the Use of Human Milk. Pediatrics. 2022;000(0):e2022057989
3. Parker MG, Stellwagen LM, Noble L, et al; AAP Section on Breastfeeding, Committee on Nutrition, Committee on Fetus and Newborn. Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant. Pediatrics. 2021;148(5):e2021054272
4. O'Connor DL, Gibbins S, et al. Effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low-birth-weight infants at 18 months: a randomized control trial. JAMA. 2016 Nov 8;316(18):1897-1905.
5. Boundy EO, Anstey EH, Nelson JM. Donor Human Milk Use in Advanced Neonatal Care Units — United States, 2020. MMWR Morb Mortal Wkly Rep 2022;71:1037–1041.DOI: http://dx.doi.org/10.15585/mmwr.mm7133a1.
6. Steele C (2018) Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants. Front. Nutr. 5:76.