Regional Need

- What non-profit and commercial milk banks provide milk in your region?
- Who is supplying level 3 and 4 NICUs?
- Are they meeting the need?
- Are donors in your region engaged?
- How much milk do they use?
- 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?

Building a Non-Profit Milk Bank

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

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

Lisa Stellwagen MD FAAP
UC San Diego Health
March 2023

UC Health is the largest academic medical center system in the US

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

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?
- Are donors in your region engaged?
- How much milk do they use?
- 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?
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 conducive to innovation programs and attract potential donors.

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.

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 reframe the budget and garner additional community support.
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 Maysen, CEO UCSD 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

Regulatory Preparation

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

Budget Preparation

<table>
<thead>
<tr>
<th>Category</th>
<th>Budget</th>
<th>Budget</th>
<th>Budget</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility site and plans</td>
<td>$500K</td>
<td>$500K</td>
<td>$500K</td>
<td>$500K</td>
</tr>
<tr>
<td>Staffing</td>
<td>$200K</td>
<td>$200K</td>
<td>$200K</td>
<td>$200K</td>
</tr>
<tr>
<td>IT needs</td>
<td>$150K</td>
<td>$150K</td>
<td>$150K</td>
<td>$150K</td>
</tr>
<tr>
<td>Operations planning</td>
<td>$100K</td>
<td>$100K</td>
<td>$100K</td>
<td>$100K</td>
</tr>
<tr>
<td>Equipment</td>
<td>$80K</td>
<td>$80K</td>
<td>$80K</td>
<td>$80K</td>
</tr>
<tr>
<td>Fitting up</td>
<td>$50K</td>
<td>$50K</td>
<td>$50K</td>
<td>$50K</td>
</tr>
<tr>
<td>Team to help you get there!</td>
<td>$30K</td>
<td>$30K</td>
<td>$30K</td>
<td>$30K</td>
</tr>
</tbody>
</table>

Building The Facility

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

- Size (UCH/M&B is 3,000 SF)
- Location
- HMB/NAH 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 ED)
- Medical Provider must sign-off donor approvals
- Milk lab staff (DTR with NICU experience)
- Staff engagement and retention
**Information Technology**
- Data tracking
- Customer engagement
- O&M
- 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?
Donor Screening

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

Milk processing

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

How Much Milk Will You Need To Collect?

- Raw milk collected (estimated vol)
- Does not meet safety standard (5-10%)
- Processing loss (1-10%)
- PDHM inventory

How Much Milk Will You Have On Hand?

- Collect 25,000 oz per month
- In House 25,000 oz raw milk
- Process 25,000 oz per month
- Inventory 25,000 oz PDHM
- Sales 21,000 oz per month
Milk Product Decisions

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

Macronutrient Content:

- 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.

<table>
<thead>
<tr>
<th>Milk Type</th>
<th>Suggested Use</th>
<th>Bottle Size mLs</th>
<th>Bottle Size oz</th>
<th>Calorie content / oz</th>
<th>Protein content / oz</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td>Outpatient</td>
<td>100</td>
<td>3.38</td>
<td>18-19 Kcals/oz</td>
<td>No target</td>
<td>$17.00</td>
</tr>
<tr>
<td>Standard NICU/Hospital</td>
<td>50</td>
<td>1.69</td>
<td>≥20 Kcals/oz</td>
<td>≥1.0 gm/dL</td>
<td>$12.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>3.38</td>
<td>≥20 Kcals/oz</td>
<td>≥1.0 gm/dL</td>
<td>$17.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>6.76</td>
<td>≥20 Kcals/oz</td>
<td>≥1.0 gm/dL</td>
<td>$32.50</td>
<td></td>
</tr>
<tr>
<td>Protein Target</td>
<td>NICU/Hospital</td>
<td>50</td>
<td>1.69</td>
<td>≥20 Kcals/oz</td>
<td>≥1.2 gm/dL</td>
<td>$13.00</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>3.38</td>
<td>≥20 Kcals/oz</td>
<td>≥1.2 gm/dL</td>
<td>$19.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>6.76</td>
<td>≥20 Kcals/oz</td>
<td>≥1.2 gm/dL</td>
<td>$37.50</td>
<td></td>
</tr>
</tbody>
</table>

Sustainability:

- Courier expenses are a flat $40 fee. Hospitals can order more milk per delivery, saving money and reducing our shared carbon footprint.
- The plastic 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 ucmilkbank.ucsd.edu.
- Executive and Medical Director — Lisa Stellwagen MD FAAP
  lstellwagen@health.ucsd.edu
- Business Manager — Sabrina Moxcey, MHA
  T: (619) 543-7076  E: smoxcey@health.ucsd.edu
- General Inquiries (858) 249-MILK (6455)

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)

Small Equipment

- Milk pots
- Spoons/Filter
- Mixers
- Dispenser
- Capping device
- Hot water bath
- Thermometers
- Autoclave
- Ozone generators
- Scales
- Label printers
- Office equipment/computers
  & etc!

Pasteurizer Choice

- Circulating water bath
- ACE (UK)
- Sterifeed (UK)
- All Holder pasteurization
- Future maybe different!
Disposables
- Bottles and caps
- Shipping boxes
- 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
- FedEx or UPS Shipping
- Packing and shipping materials
- Dry ice
- Cold chain documents
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

Marketing

Brand Guide

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!

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 H, Noble L. Breastfeeding and the Use of Human MILK. Pediatrics. 2022;000(0):e2022057989