

SUBSTUDY 12

COST-EFFECTIVENESS OF HOME VERSUS HOSPITAL SUPPORT OF BREAST FEEDING IN NEONATES

A Report Prepared for
the Health Transition Fund, Health Canada

April 2001



National Evaluation of the Cost-Effectiveness of Home Care



and



Home Care Evaluation and Research Centre
University of Toronto



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**by Home Care Evaluation and Research Centre
University of Toronto**

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April 2001



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PREFACE

The National Evaluation of the Cost-Effectiveness of Home Care is an integrated program of research with 15 studies being conducted across Canada. There is an overall strategy for the program of research to make it as useful to administrators and decision makers as possible. The program of research is designed to determine whether or not home care is a cost-effective alternative to institutional care, that is, care in long term care facilities and acute care hospitals. However, the program of research is also designed to provide an educational function to inform decision makers and the public about home care and to provide advice about issues related to implementing new and cost-effective home care initiatives. Thus, the overall strategy has the following components:

- Conduct studies to determine whether or not home care is a cost-effective alternative to institutional care, and if so, under what conditions it is cost-effective.
- Conduct studies to inform decision makers about the nature and scope of home care services across Canada. These studies provide a baseline of information about home care clients, costs, and utilization. This baseline is important because there is currently no national database on home care in Canada.
- Conduct studies to explore opportunities for potential savings in the hospital sector by substituting home care services. At present there are relatively few areas noted in the literature where home care has been shown to be a cost-effective alternative to hospital care.
- Conduct studies to provide decision makers with information about some of the issues they may face if they try to implement new initiatives to enhance the cost-effectiveness of the health care system.

This study, Substudy 12, *Cost-Effectiveness of Home versus Hospital Support of Breast Feeding in Neonates*, was designed to examine the costs associated with breast feeding of term and preterm infants in both home and hospital contexts as well as the efficacy, safety, level of maternal satisfaction and resources involved in the management of breast feeding.

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EXECUTIVE SUMMARY

Purpose of Project

The purpose of this study was to compare the cost, safety, and efficacy of supporting breast feeding in the hospital and home setting for term and preterm neonates. The overall goal was to determine the incremental costs and consequences to society associated with home-based compared to hospital-based support of breast feeding in term and preterm neonates in the first week of life. Data to support safe and efficacious management of these infants were collected.

Target Audience

This study has provided data about (a) the cost-effectiveness of managing breast feeding of term and preterm neonates in the first week of life, (b) the efficacy and safety of home care for these infants and mothers, (c) the mothers' satisfaction about hospital and home-based supportive nursing care and (d) the resources utilized by mothers of neonates while in the hospital and community settings. This work has provided insight into determining the most appropriate site for managing breast feeding problems for term and preterm neonates that may be used to establish evidence for practice (best practices). Eventually these data may contribute to the development of standards of care for these neonates and their mothers and influence the decisions of policy makers. Therefore, the target audience is broad and includes the consumer (mothers), the clinician (health care professionals), administrator (in the hospital and community), and policy makers at institutional and governmental levels.

Methodologies/Activities

A randomized control trial (RCT) design with prognostic stratification for gestational age (GA) at birth was used to study the problem. Eligible mother-infant pairs were stratified as term (> 37 weeks GA at birth) or preterm (35-37 weeks GA at birth) and randomly allocated to the experimental (EXP) or standard care (SC) group. Mother/ infants in the SC group were cared for in the hospital and were discharged using existing hospital discharge criteria at approximately 48-60 hours postpartum. Mother/infants in the EXP group were assessed at 24-36 hours postpartum and discharged home if they met the same discharge criteria. Each mother/infant pair in the EXP group was also scheduled to receive a minimum of 3 home visits from the community nurses (who were qualified as lactation consultants). Mothers in both groups were encouraged to use a preexisting 24-hour telephone help line and outpatient community breast feeding clinic. Economic and clinical (safety and efficacy) outcomes were measured at study entry (prior to randomization), at hospital discharge and at a seven-day follow-up session. Both quantitative and qualitative methods for data collection and analysis were employed.

Main Findings

The findings for the term and preterm infants were analyzed independently and therefore will be discussed separately.

Term infants

The sample for the term group consisted of 101 mother-infant dyads, of whom 53 (52.5%) were in the EXP group and 48 (47.5%) were in the SC group. **Direct family costs** (i.e., the amount by which the family and their friends paid out of pocket) and **indirect family costs** (i.e., time missed from work in the labour market, from leisure, or from household work) were determined. **Health care system costs** including **hospital delivery costs** (i.e., costs of the hospital stay, including physician fees, overhead costs, labs), **post-discharge systems costs** (i.e., other costs to the system such as nursing visits, visits to the community physicians, lab tests, readmission costs, etc.), **total system costs** (i.e., costs of the hospital delivery plus post-discharge system costs). **Societal costs** (i.e., costs include total system costs plus direct and indirect family costs) were assessed. The SC and EXP groups only differed significantly in their post-discharge system costs ($p < 0.0001$) (with greater costs to the EXP group). There was a trend towards significance in the direct family costs ($p = 0.1085$) (with greater costs to the SC group). The groups did not differ significantly in their indirect family costs, hospital delivery costs, or total system costs.

Regarding clinical outcomes, the two groups differed significantly with respect to the proportion of infants who were exclusively breast fed at the follow-up visit (< 0.0446) and the number of feeds that were exclusively breast feeding within the past 24 hours ($p < 0.0278$), with the EXP group being breast fed more exclusively than the SC group on both accounts. In relation to maternal satisfaction, the mothers who were in the EXP group, were satisfied with early discharge and the quality of the home care that they received by the community nursing agency. They identified the following advantages: they were at home in a familiar and comfortable setting; they received specialized support for breast feeding and for infant care; they could be at home with other family members and they had faster recovery. Over 50% said there were no limitations with early discharge. Others said they were fearful of leaving the hospital too soon and were concerned about their own and their baby's health, there was a lack of support at home and not enough coverage from the visiting nurse on the weekends.

The mothers in the SC group stated that the benefits were that the hospital support was accessible and the environment was controlled. They also said they had parental preparation time and breast-feeding support. On the other hand, most mothers stated that the limitations of staying in the hospital environment was that the conditions in hospital were not conducive to adequate sleep and recovery and that the hospital staff were not supportive to their or their infant's needs.

Preterm Infants

The sample for the preterm group consisted of 37 mother-infant dyads, of whom 19 (51.4%) were in the experimental (EXP) group and 18 (48.7%) were in the standard care (SC) group. The SC and EXP groups did not differ on direct costs, indirect costs, hospital delivery costs, systems costs, total systems costs or societal costs. This is most likely reflective of the lack of a significant difference in duration of hospital stay between the two groups (as the infants did not meet the predetermined discharge criteria) and the small sample size. There were no statistically significant differences in any of the clinical outcomes, although similar to the term group, the EXP group had a higher proportion of infants who were exclusively breast fed. In relation to maternal satisfaction,

the analyses of the qualitative data for the preterm group did not differ significantly from the term group, except that those mothers who were discharged early thought that the number and frequency of community nursing agency visits may not be sufficient.

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This project was also supported by a financial contribution from The Hospital for Sick Children Foundation. This joint funding allowed for the inclusion of both term and preterm infants in the study.

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INTRODUCTION

Most Canadian mothers initially intend to breast feed their infants (McNally, 1985) and whether they are born at term or preterm does not affect this decision. Substantial health care resources are expended to assist mothers to breast feed their newborn infants because successful breast feeding confers important benefits to the infant and mother. This is evidenced by a decreased risk of morbidity, hospitalization and mortality (Cunningham, 1979; Damus et al., 1988; Lucas & Cole, 1990; Howie et al., 1990; Cunningham et al., 1991; Walker, 1993).

Human milk is the most beneficial source of nutrition for infants (Winikoff & Baer, 1980; World Health Organization, 1981; Canadian Paediatric Society, 1978; American Academy of Pediatrics, 1978). Breast milk's unique nutritional (Anderson et al., 1981; Anderson et al., 1983; Atkinson, 1980; Read et al., 1985), immunologic (Goldman et al., 1982; Gross et al., 1981; Murphy et al., 1983; Narayanan et al., 1981), and anti-allergic properties (Chandra, 1979; Kramer, 1988), as well as its mode of transmission (Meier & Anderson, 1987; Meier, 1988) potentiate health outcomes in preterm neonates. In addition to physiologic benefits, some researchers have asserted that breast fed preterm infants may exhibit an enhanced developmental status (Lucas et al., 1989; Lucas et al., 1992). In addition to these positive outcomes for infants, breast feeding has been associated with significant economic advantages for families. A few studies report the potential savings to the health care system that breast feeding may confer (Salisbury & Blackwell, 1981; Facione, 1990). Infant formula has been estimated to consume 5-44% of the budget of a single parent when welfare is the sole source of income (Elston, 1993). The cost saving potential of breast feeding is underscored by the low socio-economic status of many mothers who deliver preterm. Breast feeding, therefore, is desirable in terms of both health and economic outcomes for term and preterm infants.

Despite its merits, the establishment of breast feeding within the first 72 hours of life is a challenge in full term infants and may be particularly difficult in preterm infants. Of all newborn infants in Canada, approximately 7% are born preterm. The vast majority of these are born at 35-37 weeks gestational age (GA) (Hanvey et al., 1994). Preterm infants differ from their full-term counterparts in important ways including lower birth weight, increased risk of infection, and developmental immaturity. At 35-37 weeks GA, many infants are unable to tolerate feeding effectively as the coordination of sucking, swallowing, and breathing are poorly developed until 32-34 weeks GA and slowly mature towards term and later. This immaturity often necessitates hospitalization of the infant in the unit until she/he can tolerate sufficient oral intake to be discharged home. During the infant's hospitalization, the mother also remains in the hospital in the postpartum unit for successful initiation of feeding her infant. Therefore, the establishment of breast feeding in preterm infants frequently is time consuming and resource intensive.

The importance of facilitating breast feeding the newborn is beyond dispute. Infants either remain hospitalized until breast feeding has been well established or are discharged and are referred to Breast Feeding Clinics to assist with breast feeding on an outpatient basis. However, the optimal environment and type and amount of professional support required for newborn infants and their mothers beyond the first 24 hours postpartum is not clear.

Currently, hospitals are under significant pressure to develop alternative models of service delivery. This reality has challenged administrators and health care providers to develop safe,

efficacious and cost-effective programs where all or part of an individual's care can be delivered in an alternative setting, most preferably at home. However, because home care services, as currently configured, are themselves overburdened, they may be unable to absorb additional demands. As the central focus of care provided to the hospitalized newborn and mother is support of infant feeding and assessment of the hydration status of the infant, it should be feasible to train community nurses to provide these services at home through home visits.

The purpose of this study was to compare the cost, safety, and efficacy of supporting breast feeding in the hospital and home setting for term and preterm neonates. The overall goal was to determine the incremental costs and consequences to society associated with home-based compared to hospital-based support of breast feeding in term and preterm neonates in the first week of life. Data to support safe and efficacious management of these infants were collected and analyzed.

The information collected in this study is important because:

- The cost of providing care in alternative settings for term versus preterm infants is unknown. In particular, direct and indirect system and individual costs for delivery of home care for this population are inadequately documented.
- The site of care delivery may have an important impact on infant clinical outcomes. In addition, the burden for mothers who care for the baby at home with support from community health professionals is unknown.
- There is minimal knowledge of the nature and frequency of adverse effects of care for breast feeding term versus preterm infants offered in an alternative setting as compared to the traditional institutional setting.
- The implementation of a novel service delivery model may have an impact on knowledge and resource requirements for administrators and health care providers from both institutional and community care settings. The acceptability and satisfaction with this intervention is not well understood.

METHODS

Design

This study was carried out using an integrated model of health care delivery in collaboration with both the hospital and home care agency. (There was no direct link with the Community Care Access Centers, and an agreement for the provision of home care was made directly with the home care agency). A formal agreement was established under the auspices of Research Services at the University of Toronto.

A randomized control trial (RCT) design with prognostic stratification for gestational age (GA) at birth was used to study the problem. Eligible mother-infant pairs were stratified as term (> 37 weeks GA at birth) or preterm (35-37 weeks GA at birth) and randomly allocated to the experimental (EXP) or standard care (SC) group. Mother/ infants in the SC group were cared for in the hospital and were discharged using unit discharge policies at approximately 48-60 hours postpartum. Mother/infants in the EXP group were assessed at 24-36 hours postpartum and discharged home if they met the hospital discharge criteria. Each mother-infant pair in the EXP group was also scheduled to receive a minimum of 3 home visits from the community nurses (who were qualified as lactation consultants). Mothers in both groups were encouraged to use a 24-hour telephone help line and an existing community breast feeding clinic. Economic and clinical (safety and efficacy) outcomes were measured at study entry (prior to randomization), at hospital discharge and at a seven-day follow-up period. Both qualitative and quantitative methods were used.

Economic Evaluation

Costs incurred by both families and the health care system were measured. Families documented direct (e.g. out-of-pocket costs such as paid care givers, travel expenses, non-prescription and prescription medications and supplies/equipment, and paid household caretakers), and indirect (e.g. time costs such as lost time from the labour market, leisure activities, and household work) costs. Health care system costs, including the fully allocated institutional cost, clinic costs, the cost of physicians and other health care professionals who provide home care services, medication costs, laboratory fees, and supply costs were assessed. In addition, frequency of emergency department visits, readmission to the hospital, telephone calls to the 24-hour help line, visits and telephone calls to the breast feeding clinic, and visits and telephone calls to community practitioners during the first week of the baby's life was obtained from the Day 7 Follow-up Assessment visit.

For the SC Group, a mean of the costs incurred during Day 2 (a 24-hour period) have been computed. This mean cost was obtained by collecting data on hospital admission costs (e.g., nursing costs, "hotel" costs) from the unit administrators and resource costs (e.g., supplies, medications, tests) from health professionals within the postpartum unit. Health professionals and administrators participated in a focus group that developed the template representing the types of costs associated with caring for a "typical mother-infant pair on Day 2.

For the EXP Group, all costs for home nursing visits were recorded. Health care system costs on Days 2-7 for the EXP group and Days 3-7 for the SC group have been assessed. Training costs (both one time and ongoing) for educating and orienting both hospital and community nurses were calculated. The human capital approach was used to calculate the value of the time devoted by informal care givers (Togerston et al., 1994; Rice & MacKenzie, 1989). The human capital approach applies current average earnings by age and gender to lost market time and imputes the market value of time withdrawn from leisure and household work. To do this, average national earnings by age and gender were used. Finally, societal costs (i.e., total system costs plus direct and indirect family costs) were assessed.

Clinical Evaluation

Infants

The safety and efficacy of supporting breast feeding and attending to feeding problems in both groups were assessed by measuring the infant's weight, breast feeding exclusivity, and incidence of jaundice and hydration. Weight was assessed at birth, prior to hospital discharge, and at the Day 7 Follow-up visit. Breast-feeding was assessed by the number of exclusive breast feedings within 24 hours and normal output in 24 hours. Jaundice was assessed by "flash" bilirubin level at the Day 7 Follow-up visit. Hydration was assessed by the [a] normal expected output, [b] minimum of 8 feeds/24 hours with effective suck, [c] weight loss <10%, [d] fontanelles soft and flat, [e] skin turgor good, [f] arouses easily, alert and active, and [g] sleeps between feeds.

Maternal

The mother's perceptions of the postpartum experience were obtained at the Day 7 Follow-up visit. Mothers also participated in a brief interview, describing their perceptions about the quality and adequacy of care they and their infants received during the first postpartum week. For those mothers who were in the EXP group, the home care nurse also asked them about their physical well being (i.e., bleeding, episiotomy, and condition of nipples); this was not part of the study but was done as part of routine care for the mother.

Copies of all data collection instruments are provided in Appendix A.

FINDINGS

The study findings were analyzed separately for the term and preterm infants.

Term Group

The sample for the term group consisted of 101 mother-infant dyads, of whom 53 (52.5%) were in the experimental group and 48 (47.5%) were in the standard treatment group. Six mothers withdrew from the study prior to their discharge from the hospital (4 from the experimental group and 2 were from the standard group), leaving a total sample of 95. There was no significant difference in the two groups at randomization, except for length of hospital stay, where the experimental group stayed approximately 7 hours less than the standard care group ($p=0.0166$).

Economic Outcomes

The SC and EXP groups only differed significantly in their post-discharge system costs ($p<0.0001$) (with greater costs to the EXP group). There was a trend towards significance in the direct family costs ($p=0.1085$) (with greater costs to the SC group). The groups did not differ significantly in their indirect costs, delivery costs, total system costs or societal costs.

Clinical Outcomes

Follow-up interviews were done on 88 term babies, within 10 days of the baby's birth for 68 babies, 34 in each treatment group. The main outcomes of interest were jaundice (flash bilirubin > 19), baby receiving at least 8 feeds in 24 hours, proportion of feeds which were exclusively breast fed, and normal output (at least 6 wet diapers). The two groups differed significantly only with respect to the proportion of feeds which were exclusively breast fed, with the experimental group doing better than the standard group ($p< 0.0278$). The findings are summarized in Table 2.

Maternal Outcomes

There were 88 responses to the Post Partum Questionnaire (PPQ), completed by the mothers at the 7-day follow-up visit (48 from the experimental group and 40 from the standard care group).

The Hospital Experience

The Post Partum Questionnaire contained 27 questions about the hospital nursing experience. There were only significant differences between the 2 groups on 1 question. In the experimental group 82.9% (39/47) of the patients strongly agreed with the statement (item 7), "I am very satisfied with the help I had in the first few days after we went home from the hospital", and 95.7% (45/47) agreed somewhat or strongly, compared with 52.5% (21/40) and 80.0% (32/40), respectively, in the standard care group.

Table 1: Summary of Costs by Group

Costs	Group	Mean (SD)	Min	25th percentile	Median	75th percentile	Max
Direct Family p=0.1085	EXP(n=48)	143 (114)	59	78	101	170	711
	SC (n=40)	255 (536)	0	38	85	179	3092
Indirect Family p=0.8183	EXP	1895 (1478)	372	963	1469	2370	7920
	SC	1691 (1089)	111	1018	1460	2207	5031
Hospital Delivery p=0.2198	EXP	2529 (122)	2301	2475	2496	2536	2937
	SC	2630 (308)	1902	2453	2527	2837	3603
Post-Discharge System p<0.0001	EXP	137 (89)	0	89	109	156	419
	SC	56 (61)	0	27	27	53	294
Total System p<0.3927	EXP	2666 (151)	2378	2570	2622	2749	3026
	SC	2686 (318)	1929	2490	2580	2868	3603
Societal p=0.9833	EXP	4703 (1514)	3276	3765	4282	5236	10823
	SC	4631 (1245)	2932	3789	4221	5438	7797

Table 2: Infant Clinical Outcomes

	Experimental Group (mean/SD)	Standard Care Group (mean/SD)	p value
Age at follow-up: days of age	7.8 (1.4)	7.8 (1.4)	0.9353
Age at follow-up: days since D/C	6.4 (1.4)	6.2 (1.6)	0.6453
Weight gain since birth (grams)	42.4 (197)	82.8 (181)	0.5139
% of infants with jaundice (flash bili > 19)	2/27 (7.4%)	2/29 (6.9%)	1.0000
% of feeds exclusively breast feeding in past 24 hours	97%	87%	0.0278 *
% of babies breast fed exclusively in past 24 hours	94.1%	73.5%	0.0446 *
normal output (at least 6 wet diapers in past 24 hours)	100%	91%	0.2388

Table 3: Types of Help Utilized

Types of Help	Experimental Group	Standard Care Group	Satisfaction
Public health nurse - phone	55.9%	35.3%	100%
Public health nurse - visit	0	8.8%	100%
Home care nurse - phone	91.2%	not applicable	100%
Home care nurse - visit	97.1%	not applicable	100%
Help line - hospital	20.6%	12.1%	81.8%
Help line - home care	5.9%	not applicable	50.0%
Lactation consultant	61.8%	58.8%	100%
Doctor - phone	61.8%	58.8%	97.6%
Doctor - visit	97.0%	85.3%	98.4%
Emergency room visit	12%	6%	100%
Ambulance	0	0	
Hospital admission - mother	0	0	
Hospital admission - baby	0	0	

One other item had a p-value < 0.05 and two items had p-values between 0.05 and 0.10. Item 25 ("I felt I was respected as a person") had a p-value of 0.0310. Virtually all of the patients agreed with the statement, but the experimental group was more likely to agree strongly (rather than agreeing somewhat). Item 19 ("I got enough emotional support, reassurance") had a p-value of 0.0582. Here, too, the proportion of patients agreeing was about 90% in both groups, but the experimental group was more likely to strongly agree. Item 15 ("I am happy with the way the nurses and doctors in the hospital have watched over my physical health") had a p-value of 0.0901, and this is the same thing - about 90% overall agreed with the statement, but the experimental group was more likely to strongly agree. Thus, for all but item 7, the two groups do not differ with respect to the proportion who agrees with the statements, though they occasionally differ in the strength of their agreement.

The Community Experience

Items 28 through 37 were answered by the experimental group, only. All but one said they were very satisfied with the care provided by the community nurses. One mother in the experimental group was somewhat satisfied. Mothers were also interviewed at Day 7 and asked about what they perceived the benefits and limitations were of staying in hospital longer (SC group) or leaving the hospital earlier (Experimental group). The answers are summarized in Table 4.

Preterm Group

The sample for the preterm group consisted of 37 mother-infant dyads, of whom 19 (51.4%) were in the EXP group and 18 (48.7%) were in the SC group. All mothers who were enrolled in the study remained through hospital discharge, although 8 were lost to follow-up at 7 days. There was no significant difference in the two groups at randomization, including length of hospital stay, where the mean length of stay was 49.5 hours or just over 2 days); the SC group stayed approximately 2 hours longer than the EXP group but this was not significant ($p=0.7628$).

Economic Outcomes

The SC and EXP groups did not differ significantly in relation to any costs, as defined on pages 7 and 8. The results are summarized for costs for preterm infants in Table 5.

Clinical Outcomes

Follow-up interviews were done on 27 mothers of preterm babies, within 10 days of the baby's birth for 27 babies, 12 in the standard care group and 15 in the experimental group. The main outcomes of interest were jaundice (flash bilirubin > 19), baby receiving at least 8 feeds in 24 hours, proportion of feeds which were exclusively breast fed, and normal output (at least 6 wet diapers). The two groups did not differ significantly on any clinical outcome. The findings are summarized in Table 6.

Table 4: Summary of Maternal Satisfaction

Standard Care Group	
<i>Benefits of staying in hospital longer</i>	
(1)	Allows time to build confidence in caring for baby
(2)	Doctors / Nurses are instantly accessible
(3)	Easy access to breast-feeding clinic and nursing assistance (with latching)
(4)	Too busy and stressful at home due to demands of other small children
(5)	Helpful nursing staff (those who took the time for 1:1 personal talks with moms)
<i>Limitations of staying in hospital longer</i>	
Conditions in hospital were not conducive to rest, relaxation, sleeping, constant interruptions, no control over visitors, noise, under staffing) + overall physical environment of hospital (complete lack of privacy, bad food, warm, crowding of patient rooms)	
(1)	Postpartum nursing staff were described as unpleasant, intolerant, uncaring, abrupt, non-supportive, unresponsive) + lack of consistency in nurses, staff always in a rush
(2)	Unfamiliar environment, psychologically uncomfortable, strange)
(3)	With longer stay in hospital, no opportunity for visiting nurses post D/C]
(4)	Lack of 1:1 teaching, support, information (longer stay is a waste of time)
Experimental Group	
Over 95% were satisfied with going home early; over 60% thought staying longer in hospital should be optional for first time moms if they and their husbands felt frightened to go home, felt unprepared, had little support at home, if mom or baby had health problems, if home environment was too stressful (e.g. other small children to care for)	
<i>Benefits of early D/C</i>	
Being in familiar, comfortable home environment	
(1)	1:1 support with and info about breast-feeding especially assistance with latching
(2)	Nurse is available to give personal assessment of mom's abilities to care for baby, makes suggestions, gives practical advice and demonstrations, answers questions, recommends changes, offers reassurance
(3)	Mom is able to be at home with her husband and her other children
(4)	Faster recuperation
<i>Limitations of Early D/C</i>	
(1)	No limitations (approx. 50% stated "no limitations" of going home early with visiting nurse
(2)	Mom and dad not prepared to go home due to fear and anxiety, nervousness, poorly informed by hospital staff
(3)	Primary care giver for other small children, exhaustion, stress

Table 5: Summary of Costs by Group

Costs	Group	Mean (SD)	Min	25 th percentile	Median	75 th percentile	Max
Direct Family p=0.7312	EXP (n=13)	120 (109)	23	38	61	148	374
	SC (n=11)	118 (141)	0	11	58	182	474
Indirect Family p=0.6071	EXP	1572 (645)	657	1053	1391	2309	2544
	SC	1508 (1013)	88	650	1485	2271	3240
Hospital Delivery p=0.7313	EXP	2692 (299)	2391	2540	2592	2710	3327
	SC	2686 (193)	2383	2523	2649	2827	3044
Post-Discharge System p=0.7095	EXP	256 (287)	25	102	152	277	1024
	SC	766 (1196)	0	27	77	1616	3628
Total System p=0.6888	EXP	2948 (403)	2416	2651	2862	3193	3679
	SC	3451 (1189)	2383	2638	2893	4443	6150
Societal p=0.9543	EXP	4639 (403)	3362	3920	5059	5286	5684
	SC	5077 (2082)	2471	3299	4993	6155	9553

Table 6: Infant Clinical Outcomes

	Experimental Group (n = 15) (mean /SD)	Standard Care Group (n = 12) (mean/SD)	p value
Age at follow-up: days since birth	8.1 (1.9)	8.3 (1.6)	0.6255
Age at follow-up: days since d/c	6.3 (2.4)	6.5 (1.6)	0.6255
Weight gain since birth (in grams)	- 25 (183)	+ 13 (117)	0.6468
% of infants with jaundice (flash bili > 19)	1/5 (20%)	3/5 (60%)	
% of feeds exclusively breast feeding	83%	87%	0.9285
% of babies fed exclusively using effective breast feeding	73.3%	67.7%	1.0000
normal output (at least 6 wet diapers in past 24 hours)	19/19	10/12	0.1880

The types of help that mothers used ranged from nursing care to visits to the community physician and the community emergency department. Given the small numbers involved, there were no statistical comparisons undertaken. A description of the types of help that the mothers used is included in Table 7.

Table 7: Types of Help Utilized

Types of Help	Experimental Group n = 15	Standard Care Group n = 12	Satisfaction
Public health nurse - phone	60.0%	58.3%	93.8%
Public health nurse - visit	20.0%	8.3%	100%
Home care nurse - phone	93.3%	not applicable	100%
Home care nurse - visit	100%	not applicable	100%
Help line - hospital	0	16.7%	100%
Help line - home care	6.7%	not applicable	100%
Lactation consultant	80.0%	75.0%	100%
Doctor - phone	80.0%	50.0%	83.3%
Doctor - visit	93.3%	91.7%	100%
Emergency room visit	1/15 (6.7%)	3/12 (25%)	80.0%
Ambulance	0	0	
Hospital admission - mother	0	0	
Hospital admission - baby	2/15 (13.3%)	3/12 (25%)	60.0%

Maternal Outcomes

There were 29 responses to the Post Partum Questionnaire (P.Q.), completed by the mothers at the 7-day follow-up visit (16 from the EXP group and 13 from the SC group).

The questions were divided re: the hospital experience and the community experience as described in the term group, There were no differences between the 2 groups, except on item 4, where most of the mothers in the EXP group were unhappy in the hospital (agreed with the statement) but very few of the mothers in the SC group were unhappy. For item 14, overall, the mothers agreed that they got conflicting information, but this was more so in the EXP groups (90% agreed compared with 50% in the SC group). The EXP group was also more likely to feel tired (90% disagreed that they were getting enough rest compared with 50% in the SC group). For the full term group, none of the above findings for these questions were significant, so the results should be interpreted with caution.

In relation to maternal satisfaction, the analyses of the qualitative data for the preterm group did not differ significantly from the term group, except that those mothers who were discharged early thought that the number and frequency of home visiting may not be sufficient.

FINDINGS IN RELATION TO THE HTF EVALUATION FRAMEWORK

Satisfaction with quality of services provided

As participants were randomized to either the EXP group or the SC group, participants experienced either one treatment option or the other; therefore it was not possible to compare the two options within the same participants. However, from the qualitative data collected, mothers who were in the EXP group who received home care were generally very satisfied with the quality of the nursing care they received, although they did comment that they would like extended coverage. On average, the mothers of term infants availed themselves to only 1 or 2 home visits, so the issue was not quantity of available visits but rather when these visits could be scheduled.

Access to health care services

Under current policies, these mothers and infants are not eligible for home care. Therefore, these data should form the basis for a discussion with administrators and policy makers on the advantages and limitations of this model of early discharge with home caring visiting. An alternative model would be to have hospitals cover the costs of the home visits in exchange for decreased institutional nursing care costs.

Integration with other parts of the health system and other stakeholders

The proposed model involves an integration of hospital and community care by hospital and home care nurses. This model would provide continuity of care for the recipients (mothers and infants) that may improve clinical outcomes over time and decrease use of resources. As this study did not extend beyond the first 10 days of the neonate's life, the issue of longer-term clinical and economic benefits has not been explored.

The home care services provided in this study are not normally publicly funded. However, there did not seem to be overlap with existing publicly funded services (e.g. public health department nursing services) as mothers stated that although these nurses may have called them, they did not visit and they did not address breast feeding issues. The importance of having lactation consultants or nurses with breast feeding expertise in both the hospital and home care settings should not be underestimated. The CHA principles of accessibility and universality could not be addressed in this study as we were limited to one hospital setting and one home care agency. However, nurses from the home care agency were able to provide home visiting over a large geographic area.

Health impacts and effects

There were not major differences in costs between delivery of standard care in hospital and delivery of an integrated model of care that involved both hospital and home care. However, mothers that were discharged early and followed at home by the home care nurse had greater success with breast feeding if their infants were term born, although these results need to be cautiously interpreted. This difference was less obvious in preterm infants. Generally, preterm infants were not able to be

discharged early from hospital as they did not meet the preset discharge criteria. Those that were able to be discharged early required more home visits than their term counterparts. Therefore, one is left to question whether this model of care is applicable and feasible for preterm infants.

In addition, the question of whether 7 hours earlier discharge is clinically significant is raised. It may be that standard care is so reduced that it makes little difference whether people are sent home “early” as everyone else is sent home as “early as possible”. Therefore, the real question may be related to the type of support offered following early discharge (e.g., home visits by lactation consultants or access to lactation consultants in hospital or in community breast feeding clinics).

Cost-effectiveness

Generally there were no differences in costs between the existing standard care provided in hospital and the integrated model of hospital/ home care as any savings in direct costs to the families were “washed out” by an increase in systems costs. However, given that there were no differences, one could ask whether individual families should be given a choice as to the most appropriate model of care for them. This choice could facilitate greater levels of satisfaction for the health care consumer, health care professional and administrators alike. It is not known if this lack of difference in costs was related to the study being under-powered, decreased enrolment in the preterm group, and/or there were no true differences.

Transferability/Generalizability

Given our ability to acquire the desired study sample of term infant/mother dyads in a reasonable amount of time (*with a refusal rate of approximately 33%*), it would seem like this integrated model of health care is feasible and desirable for this population. However, this ease of obtaining the desired sample size for the preterm group was not apparent. Given the smaller number of infants available, the added number of factors that lead to exclusion (e.g. multiple births, illness of mother and infant), this model may not be desirable for the majority of preterm infants.

This model required a well established relationship with the home health care agency and the willingness of intermediary organizations (e.g. the community care access center) to allow direct negotiation between the hospital and home health care provider. Furthermore, ongoing communication and collaboration between the hospital and home care agency was essential for the success of the model of care and is responsible for whatever level of success was achieved.

RECOMMENDATIONS AND POLICY IMPLICATIONS

This study has provided data about (a) the cost-effectiveness of managing breast feeding of term and preterm neonates in the first week of life, (b) the efficacy and safety of home care for these infants and mothers, and (c) the mothers' satisfaction about hospital and home-based nursing care and (d) resources utilized by mothers of neonates while in the hospital and community settings. This work has provided insight into the most appropriate site for managing breast feeding problems for premature neonates that may be used to establish evidence for practice (best practices). Eventually these data may contribute to the development of standards of care for these neonates and their mothers and aid the decision-making of consumers, clinicians, administrators and policy makers.

There were very few statistically significant differences between the EXP and SC groups in terms of the economic and clinical outcomes. *For the term group*, the cost savings of direct costs for the EXP group (who were, on average, discharged approximately 7 hours earlier than the standard care group) were nullified by the increased systems costs, resulting in no significant difference in total systems costs between the two groups. An important significant clinical difference was that more infants were exclusively breast fed at follow-up, with a significantly greater percentage of infants in the term group EXP group who were exclusively breast fed. There were no significant differences in maternal satisfaction on the quantitative measure, although the qualitative data appear to support early discharge from hospital with home visiting by the community nurses. *For the preterm group*, there was no significant difference in the length of stay (approximately 2 hours shorter for the experimental group). Consequently, there were no differences in any direct, indirect, system or total systems costs or clinical outcomes. However, exclusive breast feeding was generally less in the preterm group than the term group with 73.3% of the EXP group and 67.7% of the SC group being exclusively breast fed.

Although the generalizability of these results is limited as this study was conducted in one metropolitan teaching hospital and on one postpartum unit, with a limited sample size, the recommendations may be the following:

1. Home support for breast feeding appears to be a viable option in terms of costs and clinical outcomes for mothers of term infants. Therefore we would recommend that these mothers could be offered a choice of either SC or early discharge with home visits by a lactation consultant or nurse with breast feeding expertise. This recommendation will raise issues as to who would pay for the community services (e.g. institution, community agency or third party provider) and how these would be organized within the current administrative structure of the community and hospital settings. The preterm infants were generally unable to meet the hospital criteria for early discharge. Those who did meet the criteria had similar clinical outcomes and patterns of maternal satisfaction as mothers who had standard care. The suitability of an early discharge model of care delivery for mothers of preterm infants requires further investigation.

2. The issue of whether these mothers would qualify for home care under the current home care policies would need to be challenged. If they were considered eligible for home care, the question of who could provide this service within the agency (e.g. lactation consultants or registered nurses) needs to be addressed and which service would be most appropriate (e.g. community nursing agency or public health department).
3. Best practice for infant feeding is breast feeding. However, the mothers appear to require more support in terms of breast feeding, particularly within the institutional setting, where there is less opportunity for privacy and consistency and time from health professionals. The question of how to enhance the provision of care in the institutional (e.g., in terms of privacy, noise levels, quality of nursing care) and community (e.g., availability of nursing care) settings requires attention. Furthermore, the question of how existing breast feeding services are being utilized and how effective they are in terms of clinical outcomes requires more study.

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APPENDIX A

Data Collection Instruments

Chart Abstraction/Referral Form
(Developed by Stevens et al., 1999)

Date of Data Collection (in dd/mm/yy format): _____

Mother & Infant Data:

1. Maternal birth date & parity (in dd/mm/yy format): _____ G__ T__ P__ A__ L__

2. Was labour spontaneous? 0 No 1 Yes

3. Was labour induced? 0 No 1 Yes

4. Was labour augmented? 0 No 1 Yes

5. Contractions started at (in dd/mm/yy format): _____ time ____:____

6. Membranes ruptured at (in dd/mm/yy format): _____ time ____:____

7. Type of delivery: 1 Spontaneous Vaginal 2 Vacuum Assisted 3 Forceps Assisted
4 Breech

8. Episiotomy/Laceration/Tear _____ (degree) 9. Estimated blood loss _____ mls

10. Maternal Analgesia/Anesthesia: 1 None
2 Epidural: Continuous PCEA
3 Combined Spinal/Epidural
4 IM Analgesia/Sedation:
Nubain Morphine Demerol
5 IV Analgesia/Sedation: Fentanyl Demerol
6 Other: _____

11. Date & time of birth (in dd/mm/yy format): _____ time ____:____

12. Gestational Age at birth: _____ completed weeks
LMP: _____ EDC: _____ Revised EDC by U/S: _____

13. Birthweight: _____ grams 14. Gender: 1 Male 2 Female

15. Apgar Score: ____ @ 1 min ____ @ 5 min

16. Study Group: 1 Experimental Group 2 Standard Treatment Group

17. Date & time of hospital discharge (in dd/mm/yy format): _____ time ____:____

18. Weight at discharge from the hospital: _____ grams

19. Coombs _____ Blood type _____ 20. Bilirubin at discharge from hospital: _____

21. Date PKU/Thyroid screen done (in dd/mm/yy format): _____

22. Circumcision: 0 No 1 Yes 2 N/A

Breastfeeding Plan:

1. Is baby breast feeding effectively? 0 No 1 Yes

2. If baby is NOT breast feeding effectively, what alternate method(s) is mother using?

1 Finger feeding

2 Cup feeding

3 Lactation aid

4 Bottle

5 Pumping

Please specify breast feeding plan:

Any other comments that would be helpful for the Community Nurse to know:

Community Nursing Agency Nurses Documentation of Visits

(Developed by Stevens et al., 1999)

	Visit #1	Visit #2	Visit #3	Visit #4
Date of Visit (dd/mm/yy) Time of Visit (24 hr time clock)				
Is baby jaundiced?	Yes No	Yes No	Yes No	Yes No
Baby's Hydration - # feeds exclusive breastfed/past 24 hrs				
- # feeds with supplement/past 24 hrs (specify amt/type of supplement)				
- # wet diapers/past 24 hrs				
- # & colour of stools/past 24 hrs				
- fontanel soft & flat	Yes No	Yes No	Yes No	Yes No
- skin turgor good	Yes No	Yes No	Yes No	Yes No
- arouses easily, alert, active	Yes No	Yes No	Yes No	Yes No
- sleepy/satisfied between feeds	Yes No	Yes No	Yes No	Yes No
Breastfeeding Assessment [<i>score 0, 1, or 2</i>] L (latch) A (audible swallows) T (type of nipple) C (comfort) H (hold)				
Condition of Mom's breasts 1 = soft/filling; 2 = full; 3 = engorged				
Condition of Mom's nipples 1 = non-tender; 2 = tender; 3 = blistered; 4 = bruised; 5 = cracked/bleeding				
Amount of vaginal bleeding (per Mom's report)				
Additional comments				

Day 7 / Breast Feeding Clinic Follow-up Data Collection Form

(Developed by Stevens et al., 1999)

1. Today's date and time (in dd/mm/yy format): _____ time ____ : ____
2. Location of the interview: 1 Hospital BF Clinic
2 In mother's home
3. Infant's weight today: _____ grams
4. Jaundice: _____ Flash bilirubin level
If > 19, bilirubin level _____
5. Hydration:
_____ 5.1 # of feeds in past 24 hrs w/effective suck/breastfeeding
exclusively
_____ 5.2 # of feeds in past 24 hours with supplementation
0 No 1 Yes 5.3 normal expected output
- # wet diapers in past 24 hours _____
- # and colour of stools in past 24 hours _____
0 No 1 Yes 5.3 fontanel soft and flat
0 No 1 Yes 5.4 skin turgor good
0 No 1 Yes 5.5 arouses easily, alert and active
0 No 1 Yes 5.6 sleepy and satisfied between feeds
6. Breastfeeding assessment today:
0 No 1 Yes 6.1 Exclusive breastfeeding
0 No 1 Yes 6.2 Breastfeeding with supplementation
0 No 1 Yes 6.3 Supplementation
7. Follow-up Plans:
0 No 1 Yes 7.1 No specific follow-up needed
0 No 1 Yes 7.2 Breastfeeding Clinic at hospital on _____
0 No 1 Yes 7.3 Community Nursing Agency Nurse to visit on _____

8. I would like to ask you several questions about types of help that are available for new mothers. You may have had some but not all of them in the first week after your baby was born. Please rate your satisfaction with the help you had, by responding to the statements below. Here is how to rate them.

Key:

0 = Did not have it

1 = Had it and very dissatisfied

2 = Had it and somewhat dissatisfied

3 = Had it and somewhat satisfied

4 = Had it and very satisfied

8.1 Telephone conversation with public health nurse

0 1 2 3 4

8.2 Visit(s) by public health nurse

0 1 2 3 4

8.3 Telephone conversation with community nursing agency nurse

0 1 2 3 4

8.4 Visit(s) by community nursing agency nurse

0 1 2 3 4

8.5 Help Line at the baby's birth hospital (a special hospital telephone number for new mothers)

0 1 2 3 4

8.6 Help Line at community nursing agency nurse (a special telephone number for new mothers)

0 1 2 3 4

8.7 Lactation consultant or breastfeeding support team

0 1 2 3 4

Specify where the lactation consultant was from: _____

8.8 Telephoned my doctor or my baby's doctor

0 1 2 3 4

The reason for the phone call: _____

8.9 Visit to doctor or after-hours clinic

0 1 2 3 4

The reason for the visit: _____

- 0 No 1 Yes 8. Family member who doesn't like it that I'm breastfeeding
0 No 1 Yes 9. Other (please specify): _____

10. Are you still breastfeeding?
0 No 1 Yes

If Yes, you are still breastfeeding this baby,

- 10.1 Do you have breastfeeding problems now?
0 No 1 Yes
If Yes, please describe:

- 10.2 Has your baby been given supplementation of any kind in the past 24 hours?
0 No 1 Yes

10.2.1 *If Yes, your baby was given supplementation in the past 24 hours, how did you give the supplementation?*

- 0 No 1 Yes 1. Finger feeding
0 No 1 Yes 2. Cup feeding
0 No 1 Yes 3. Lactation aid
0 No 1 Yes 4. Bottles
0 No 1 Yes 5. Other (please specify type): _____

10.2.2 What liquid did you supplement your baby with in the past 24 hours?

- 0 No 1 Yes 1. Expressed breast milk
0 No 1 Yes 2. Formula (please specify type): _____
0 No 1 Yes 3. Sugar water
0 No 1 Yes 4. Sterile water
0 No 1 Yes 5. Other (please specify type): _____

10.2.3 How much supplement have you given your baby in the past 24 hours? _____

If No, you are no longer breastfeeding this baby,

10.3 When did you stop breastfeeding?

- 0 No 1 Yes 1. During day 1 - 2 at home
- 0 No 1 Yes 2. During day 3 - 4 at home
- 0 No 1 Yes 3. During day 5 - 6 at home

10.4 Why did you stop breastfeeding?

- 0 No 1 Yes 1. I was having problems with it.
- 0 No 1 Yes 2. I was too tired.
- 0 No 1 Yes 3. I did not enjoy it.
- 0 No 1 Yes 4. Family members were not supportive.
- 0 No 1 Yes 5. My baby never seemed to be satisfied; I didn't have enough milk.
- 0 No 1 Yes 6. I was advised to stop breastfeeding
By whom? _____
- 0 No 1 Yes 7. Any other reason (please explain): _____

10.5 Do you have any additional information about your breastfeeding experience with this baby during the first week of his/her life that you would like to share with us?

- 0 No 1 Yes

Thank you for your participation in this research study.

Mother's Interview Guide
(Developed by Stevens et al., 1999)

I would like to thank you for taking the time to complete all of the forms during the study. This session is a little different in that it provides you with an opportunity to talk about whether or not it is beneficial for mothers and their babies to stay in the hospital for an extra 24 – 36 hours or go home early and have visiting nurses come into your home. We are trying to determine the strengths and limitations of each method of providing care to you and your baby. I would like to remind you that we will be taping our conversation. Is it still OK with you? Even though our conversation will be taped, we will not use your name in any written transcripts.

Based on your experience over the past week, what is your opinion about whether or not it is beneficial for mothers and their babies to stay in the hospital for an extra 24 hours or go home early and have visiting nurses come into your home?

What were the benefits of your experience?

What were the limitations of your experience?

Would you do this again? Would you recommend it to a friend?

Were you satisfied with this new mode of care?

Is there anything else you would like to say that we haven't talked about?

Thank you for your participation in this study.