Randomised controlled trial of effect of Baby Check on use of health services in first 6 months of life

Hilary Thomson, Sue Ross, Philip Wilson, Alex McConnachie, Richard Watson

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Department of General Practice, University of Glasgow, Woodside Health Centre, Glasgow, G20 7LR
Hilary Thomson, *research fellow*
Sue Ross, *lecturer in health service research*
Philip Wilson, *senior research fellow*
Alex McConnachie, *statistician*
Craigallian Surgery, 11 Craigallian Avenue, Glasgow G72 8RW
Richard Watson, *general practitioner*
Correspondence to: H Thomson, Department of Community Health Sciences, General Practice Primary Care Research Group, University of Edinburgh, Edinburgh EH8 9DX
Hilary.Thomson@ed.ac.uk

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Abstract

Objective To evaluate the effect of Baby Check, an illness scoring system for babies of 6 months or less, on parents' use of health services for their baby.
Design Randomised controlled trial.
Setting 13 general practices in Glasgow.
Subjects 997 newly delivered mothers, randomised to receive either Baby Check and *Play It Safe*, an accident prevention leaflet (n = 497), or *Play It Safe* alone (control group, n = 500).
Main outcome measures Data on consultations and referrals extracted from general practice notes after 6 months.
Results At the time of recruitment, maternal characteristics were similar for both groups (mean maternal age 29 years; deprivation categories 6 and 1 in both groups; 424 (45%) mothers were primiparous). At 6 months, general practice notes were available for 467 (94%) of the Baby Check group and 468 (94%) of the control group. The number of general practitioner consultations did not differ between the groups: median number of consultations was 2 (interquartile range 1 to 4) in the Baby Check group, and 2 (1 to 3) in the control group. Use of out of hours services did not differ significantly between the two groups (86 *v* 85; P = 0.93).
Conclusion Distributing Baby Check to an unselected group of mothers does not affect use of health services for infants up to 6 months of age.

Introduction

Assessment of illness in babies is difficult for both mothers and general practitioners and is a common source of anxiety.[1] Symptoms which have been associated with the onset of serious illness are too common for use as predictive markers.[2] Baby Check, an illness scoring system, was developed to help both mothers and health professionals assess the severity of illness in babies aged 6 months or less. Nineteen symptoms and signs were identified, which in combination were associated with serious illness.[3] The *Baby Check* booklet for parents comes with detailed instructions for use and suggests when to consult a doctor or health visitor. No professional instruction is required. The booklet has been extensively used and found to be acceptable by parents from a wide range of social backgrounds.[4 5]

The favourable reports of *Baby Check* have produced interest in distributing this booklet to all newly delivered mothers. There have, however, been no published evaluations of the effect that *Baby Check* might have on parents' response to illness in their infants and subsequent help seeking behaviour. To determine whether distribution of *Baby Check* to an unselected group of mothers has any effect on the use of general practitioner services for their infants, we carried out a randomised controlled trial of the booklet.

Subjects and methods

Thirteen practices in the south east area of Glasgow (53 general practitioners) agreed to participate in the study, of which 11 were accredited as training practices for general practitioner registrars. Practice sizes ranged from 4400 to 11 000 patients. Ethical approval was obtained for the study from the Greater Glasgow community and primary care local research ethics committee.

The mothers of all new babies born in the participating practices over 14 months were eligible for inclusion in the study unless the general practitioner or health visitor thought the mother or baby too sick for inclusion or the mother did not speak English (because *Baby Check* is written in English). Mothers who delivered more than one baby during the study were recruited once, and only the first child of a multiple birth was included. Mothers were identified by the practice manager or health visitor in each practice using the birth notification form. A copy of the form detailing mother's name, address, date of birth, parity, and date and mode of delivery and baby's sex, gestation, and weight at birth was passed to the researcher.

After stratification by practice, computer generated random numbers were used to randomise each mother to the Baby Check group or the control group. All mothers received a letter from their practice explaining that a study of the health of babies and the value of advice leaflets was being carried out and that data would be collected from their baby's case notes. A copy of an accident prevention leaflet *Play it Safe* was included with the letter for both groups of mothers, and the intervention group were also sent a copy of *Baby Check*. Practice staff were not informed of the group to which families had been allocated. Mothers who did not wish to participate in the study were invited to inform their practice.

website *e*xtra

A flow chart of the study is available on the BMJ's website

www.bmj.com

Table 1 Baseline characteristics of mothers and babies recruited to study. Values are numbers (percentages) unless stated otherwise

Characteristic	Baby Check group (n=497)	Control group (n=500)
Maternal characteristics		
Age (years):		
Mean (SD)	29.0 (5.4)	28.6 (5.4)
Range	16 to 43	15 to 43
Missing data (No)	30	29
Deprivation category:		
Affluent	156 (31)	159 (32)
Intermediate	135 (27)	129 (26)
Deprived	206 (41)	212 (42)
Parity:		
First live child	220 (46)	211 (44)
More than one	263 (54)	269 (56)
Not known	14	30
Delivery type:		
Vaginal	379 (80)	392 (84)
Caesarian section	68 (14)	59 (13)
Emergency caesarian	24 (5)	15 (3)
Not known	26	34
Feeding at discharge:		
Breast	225 (49)	221 (48)
Bottle	231 (51)	240 (52)
Not known	41	39
Baby characteristics		
Sex:		
Male	261 (53)	263 (53)
Female	228 (47)	234 (47)
Not known	8	3
APGAR score at 5 min:		
<9	23 (5)	18 (4)
⩾9	416 (95)	432 (96)
Not known	58	50
Gestation:		
Premature	23 (6)	19 (5)
Term	368 (94)	386 (95)
Not known	106	95
Birth weight:		
<2500 g	26 (5)	26 (5)
⩾2500 g	451 (95)	454 (95)
Not known	20	20

Six months after the birth, general practice notes were reviewed for details of health service use, including the number of, reason for, and outcome of all consultations (for example, prescriptions, referrals). In addition, we sent a questionnaire asking about use of *Baby Check* and other sources of the booklet to mothers at 6 months to check for cross contamination in the control population.

We assigned a deprivation category for each infant using the Carstairs postcode linked deprivation categories for the mother's residential postcode.[6] The seven categories were combined into three groups: affluent (categories 1 and 2), intermediate (categories 3, 4, and 5), and deprived (categories 6 and 7). Prematurity was defined as less than 37 weeks' gestation and low birth weight as less than 2500 g, as defined by the information and statistics division of the NHS in Scotland. Prescriptions were categorised by using section headings from the *British National Formulary*.

Data were managed and analysed with SPSS for Windows.[7] The primary analysis compared intervention and control groups on an intention to treat basis, thus allowing the value of Baby Check to be evaluated in pragmatic daily use. The main outcome was consultation rate, with secondary outcomes relating to the characteristics of the consultation. Because the distributions of these outcomes were skewed, the median number of consultations in each group were compared by the Mann-Whitney test.

Sample size was calculated before the study. A sample of 1000 babies (allowing for 10% attrition) was required to detect a 10% relative difference in consultation rates at a significance level of 5% with 80% power, based on the average number of consultations in infants up to 6 months of age established in a pilot study. A trial of this size also has 80% power to detect absolute differences of 6% in categorical variables such as the proportion of babies who had received at least one out of hours general practice consultation or referral to secondary care.

Results

Participant flow and follow up

Of the 1010 deliveries over the 14 month recruitment period, 1004 were eligible for the study. Seven were excluded: one mother declined to participate, two infants were adopted, two mothers were not traceable, and the study office was notified too late to include two mothers. The remaining 997 mothers were randomised, 497 to the Baby Check group and 500 to the control group (see *BMJ*'s website).

At the time of recruitment, maternal and baby characteristics were similar in the two groups (table 1). At 6 months, 26 (5%) of the control mothers reported having seen *Baby Check* from another source.

Table 2 Numbers of consultations with health services for babies in first 6 months of life

Consultations	No in Baby Check group (n=467)	No in control group (n=468)	Mann-Whitney test
Total*:			
0	80	90	
1	101	99	
2	78	83	
3	53	58	z=1.13,P=0.26
4	53	51	
⩾5	102	87	
General practice:			
0	89	96	
1	106	107	
2	87	89	
3	56	68	z=–1.05,P=0.30
4	49	42	
⩾5	80	66	
Out of hours:			
0	381	383	
1	63	62	
2	19	17	z=–0.09,P=0.93
3	3	6	
4	1	0	
Referrals:			
0	402	398	
1	59	62	
2	6	7	z=0.47,P=0.64
3	0	1	

*Total consultations includes general practitioner consultations, out of hours consultations, and accident and emergency visits.

Table 3 Number of babies with specific diagnoses in first 6 months of life

Diagnosis	Baby Check group (n=467)	Control group (n=468)	Mann-Whitney test
Respiratory:			
0	225	232	
1	124	140	
2	65	50	
3	33	22	z=−0.92,P=0.36
4	11	15	
⩾5	9	9	
Skin:			
0	310	323	
1	104	93	
2	28	30	
3	12	10	z=−0.79,P=0.43
4	8	5	
⩾5	5	7	
Gastrointestinal:			
0	360	358	
1	63	68	
2	20	29	
3	14	11	z=0.07,P=0.94
4	9	1	
⩾5	1	1	
Eye:			
0	395	394	
1	61	58	
2	9	12	
3	2	3	z=0.23,P=0.82
4	0	0	
⩾5	0	1	
Other:			
0	343	356	
1	91	85	
2	23	19	
3	5	4	z=−0.97 p=0.33
4	3	2	
⩾5	2	2	
No abnormality:			
0	365	374	
1	75	73	
2	24	18	
3	1	1	z=−0.72 p=0.47
4	2	1	
⩾5	0	1	

Health service use

General practitioner case note data were retrieved for 94% of both the intervention and control group (935/997): no differences were detected between groups in the use of primary care services, excluding child health surveillance and immunisation attendances (table 2). One sudden infant death occurred in the control group. In both groups, the median general practice consultation rate was two consultations during the first 6 months of life (interquartile range 1 to 4 in Baby Check group, 1 to 3 in control group), with 170 (18%) having no contact at all. Out of hours general practitioner consultations were recorded for 171 (18%) of the babies.

Characteristics of the consultation

For the 935 case notes retrieved there were 2566 recorded health service contacts in the first 6 months of life. There were no significant differences in the distribution of diagnoses (table 3). Respiratory problems were most commonly diagnosed, with 242 (52%) babies in the Baby Check group and 236 (50%) in the control group receiving a diagnosis related to a respiratory condition.

Broad categories of the outcomes of consultation did not differ for the two groups (table 4). Over a third of consultations resulted in advice on home management or plans for review and observation without a prescription or further investigation. Few children (67, 7%) were admitted to hospital. There were 150 referrals to secondary care, of which 72 (48%) were emergencies. Fifty seven (6%) children had further investigations in primary care.

More than half of consultations resulted in a prescription; most were for oral antibiotics, with topical skin preparations being the second commonest prescription (table 5). A third of babies received at least one prescription for an oral antibiotic in the first 6 months of life. Of the 339 prescriptions for oral antibiotics, respiratory disorders accounted for 278 (82%). Fifteen (4%) of the prescriptions were for treatment of otitis media, and 19 (6%) for tonsillitis or throat infections. One hundred (29%) prescriptions were for lower respiratory tract disorders and 144 (42%), for croup, coryza, and other upper respiratory tract disorders.

Discussion

Our randomised controlled trial successfully recruited and followed up 93% of the babies of eligible mothers born in 13 Glasgow practices and included a broad spectrum of socioeconomic backgrounds. We detected no change in parents' use of general practitioner services for their babies in the first 6 months of life as a result of Baby Check.

Previous research found that parents would like more information and guidance about the identification of illness and appropriate response to illness in young babies.[1 8] Baby Check is designed to provide

Table 4 Outcome of general practice consultations in first 6 months of life

Outcome	Baby Check group (n=467)	Control group (n=468)	Mann-Whitney test
Prescriptions:			
0	146	165	
1	113	117	
2	66	81	
3	51	35	z=−2.01,P=0.04
4	39	28	
⩾5	52	42	
Advice only:			
0	202	190	
1	131	147	
2	70	70	
3	34	33	z=0.36,P=0.72
4	13	19	
⩾5	17	9	
Referral, admission, or investigations:			
0	362	355	
1	71	71	
2	26	34	
3	5	7	z=0.68,P=0.50
4	3	0	
⩾5	0	1	

Each consultation could result in more than one outcome. Babies who had no general practitioner consultation are included as the analyis is done on an intention to treat basis.

Table 5 Number of babies who received prescriptions for different categories of drugs

Drug type	Baby Check group (n=467)	Control group (n=468)	Mann-Whitney test
Oral antibiotic:			
0	306	342	
1	119	92	
2	33	23	z=–2.42,P=0.02
3	7	10	
4	2	1	
Topical skin preparation:			
0	376	378	
1	54	39	
2	16	23	
3	10	17	z=0.11,P=0.91
4	3	3	
⩾5	8	8	
Anti-infective eye preparation:			
0	382	385	
1	67	71	
2	16	11	z=–0.27,P=0.79
3	2	1	
Analgesic:			
0	400	404	
1	46	55	
2	18	8	
3	1	1	z=–0.44,P=0.66
4	1	0	
⩾5	1	0	
Nose drops:			
0	403	422	
1	52	39	z=–1.86,P=0.06
2	12	7	

Infants may have received more than one item on a prescription.

such guidance and to reassure parents that their baby is not severely ill.[4] Baby Check is targeted at parents in the general population and has been found to be well accepted[4] and to empower mothers.[5] We chose to recruit mothers from a wide range of social backgrounds, distributing the booklet without further input from health professionals, because we felt this would reflect the process if Baby Check was routinely distributed. Our approach was more focused than that taken by the Royal College of General Practitioners, which includes the Baby Check items in its leaflet *When To Consult a General Practitioner*, which is directed at all the general public.

Recognition and response to illness

Although Baby Check is aimed at the general population of parents, its development was based on the identification of predictive signs and symptoms of acute systemic illness. We found that Baby Check had no significant effect on parental use of health services for their babies. We interpret this finding as indicating that Baby Check had little effect on parental recognition and response to mild illness and did not reassure parents sufficiently to alter help seeking behaviour. In common with Holmes, we found that only a small proportion of parents consulted more than four times in 6 months.[9] Holmes also found that most parents managed illness appropriately at home for a few days without professional advice. Because of the general nature of our sample, few babies became severely ill over the first 6 months of life, and it may be among this group that Baby Check would have had the greatest effect on help seeking behaviour.

Outcome of consultations

Response to illness was measured in our study by contact with the health service. This is a blunt instrument to measure parental behaviour, and we are not able to comment on how parents managed illness before a consultation. However, we collected detailed information on the nature and outcome of consultations. The proportion of consultations resulting in no action (representing the least severe illness) and the proportion resulting in referral to secondary care (representing the more severely ill babies) did not differ between the groups, suggesting that the spectrum of illness presenting to the general practitioner was similar for both groups. Prescribing outcomes varied slightly between the groups: more babies in the Baby Check group had been prescribed antibiotics. However, because of the number of comparisons performed on the data it is not possible to conclude that there is a difference between the groups.

We were surprised at the high overall level of prescribing of oral antibiotics for respiratory tract disorders, most of which are likely to be of viral origin. In a randomised controlled trial of prescribing strategies for sore throat, Little and colleagues have shown that such prescribing behaviour is likely to "medicalise" self limiting illness, resulting in increased reattendance and prescribing.[10 11] Reinforcement of this nature may have influenced our results. Further work is required to clarify the effect of prescribing for infants on parental consulting behaviour.

Baby Check as a parent held guideline

Baby Check, which comprises a series of systematically developed statements to assist parents making decisions about appropriate health care and help seeking for illness in infants, is a patient held evidence based guideline.[12] An increasing number of healthcare funders and providers use information to try to modify self care and health care demand.[13] The Dutch booklet *What should I do?*, which advises on home management and response to common illnesses, has been claimed to be acceptable to users and to reduce general practitioner consultation rates by 8%,[14] although rigorous evaluations have not been published. Studies showing the effect of patient held guidelines are scarce, but information which is relevant, accessible, meaningful, and integrated with formal health care is thought to be important.[13]

Effective dissemination and implementation strategies have proved important in ensuring that clinical guidelines are put into practice,[15] and such issues should be considered for patient held guidelines. Endorsement and reinforcement by a health professional may be particularly important in the dissemination of patient held guidelines.[16] Information may be interpreted differently by different people,[13] and its use will be influenced by unpredictable contextual factors, such as emotional state.[17] Baby Check may prove most valuable to a subset of parents who would benefit from a more intense implementation strategy. The identification of such a group is an important area for further study.

Key messages

- Baby Check is an illness scoring system designed to help parents assess the seriousness of acute illness in infants aged 0-6 months
- In our study population Baby Check had little effect on recognition and response to illness as measured by use of health services
- A third of babies in both groups received at least one prescription for antibiotics in the first 6 months of life
- Introducing Baby Check introduced as a routine part of child health care without further endorsement would not alter demand for health services

We conclude that distributing illness assessment guidelines to an unselected group of mothers may be well received[4 5] but tangible benefits to the parents, babies, or health care providers are difficult to detect. Introducing Baby Check as a routine part of child health care would not change demand for services.

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A lesson learnt

A painful lesson

I sustained a spiral fracture of my tibia while on holiday when I was 14. This was manipulated under sedation, and I was admitted to the local hospital in the south of England. I passed a sleepless night in great pain when the analgesia I had been given for the manipulation wore off. The next morning I was still in too much discomfort to use crutches, and the friends, with whom I had been on an organised adventure holiday, returned home.

I had to wait in hospital until I was fit enough for my parents (who remained in the north looking after my younger sisters) to pick me up and take me home. This took some six days; I was in absolute agony for the entire period. Members of staff could not understand why I was unable to get up on crutches and why during the day I constantly requested a repositioning of my leg on a stack of pillows, while at night I lay awake fretfully.

These were some of my darkest days. I was confined to a bed in too much pain to move, in a strange town with no visitors. I was told that I had a "low pain threshold" and it deepened my despair to think that I was in some way responsible for my predicament.

Eventually, I was able to be carried to my parents' car and driven home. A bed was erected for me downstairs, and I left it twice a day to be helped to the toilet. The pain persisted.

After a week or so I had to be carried to an ambulance for the fracture clinic appointment in the local hospital. I had an *x* ray examination and the consultant examined the films in amazement. The leg had been set in such away that the two fractured ends of the bone were lying one on top of the other instead of end to end. He explained that without immediate surgery the affected leg would be several inches shorter than its fellow. He also wondered how I had tolerated the pain that this must have been causing for nearly three weeks.

The fracture was reset and internally fixed with a screw the next morning. On the first postoperative day I was up on crutches and made an uncomplicated recovery.

To me, there is no such thing as a "pain threshold." Pain is debilitating and extremely distressing. Even the most doubtful of patients, as I must have seemed, should be given the benefit of a careful consideration before dismissing their symptoms. When there seems little that can be done to make somebody more comfortable, either by analgesia or non-pharmacological means, a sympathetic, understanding, and supportive attitude is vital.

Solomon Almond, *lecturer in pharmacology, Liverpool*