How to deal with an unsettled infant

All infants fuss sometimes and have occasional periods of unsoothable crying, but in most this behaviour resolves by a few months of age. The challenge for GPs is to identify, investigate and manage those few infants who are not following the normal cry/fuss neurodevelopmental pattern.

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Defining the unsettled infant

Negative vocalisations by infants have been described as fussing, unsettledness, crying, screaming and 'colic', with most descriptions recognising a progression from fussing to crying to screaming, although there is no agreed definition. What one parent sees as fussing or crying, another sees as distress or the baby being in pain. Similarly, research protocols have used more than 10 definitions of fussing and crying to identify different groups of infants[1] and this has hindered attempts to profile fussy infants and compare intervention effects.

This is one reason why estimates of the prevalence of colic in infants range from 8 to 40%. However, most work confirms early observations that the duration of infant crying and fussing increases from 2 weeks of age (adjusted for prematurity), peaks at about 6 to 8 weeks of age and decreases by 50% by 3 months of age (Figure 1).[2] Those infants in the upper-quartile range of normal have more frequent, longer, nonresponsive bouts of crying at 6 weeks of age and cry or fuss for more than three hours a day.

Fussing and crying bouts become shorter and more responsive by 5 months of age, although they remain more frequent in unsettled infants. The behaviour 'tracks' or continues over time, and infants who have a 'difficult' temperament at 2 weeks of age are likely to cry or fuss for more hours each day at 6 weeks of age.[3] The other characteristics of an unsettled infant are the clustering of unsettledness in the early evening and the large day-to-day variation in unsettledness. Infant crying characteristically induces maximal responses from the primary carer.

For research purposes, the most commonly used definition of negative vocalisation is based on that given by Wessell:[4] 'A "fussy" infant was defined as one who, otherwise healthy and well-fed, had paroxysms of irritability, fussing or crying lasting for a total of more than three hours a day and occurring on more than three days in any one week.' This is, however, an arbitrary definition that does not always correlate with parental concern about excessive crying.[5] In one case series, only one-third of infants considered to be 'colicky' by

IN SUMMARY

- **It is normal for some infants to fuss or cry for more than three hours a day at the peak age for unsettledness, about 6 to 8 weeks of age (adjusted for prematurity).**
- **No medical or parental cause for the unsettled behaviour will be found in the majority of cases.**
- **No investigations or medical interventions are required for most infants, other than providing reassurance and coping strategies for the parents in these difficult situations.**

their mothers met the 'rule of three' criteria of excessive crying for three hours a day, three days a week, for three consecutive weeks when parental diaries were kept.[6] What is clinically important is not only whether an infant's crying and fussing falls within the normal developmental pattern, but also the parents' reactions to the behaviour.

The role of the parents

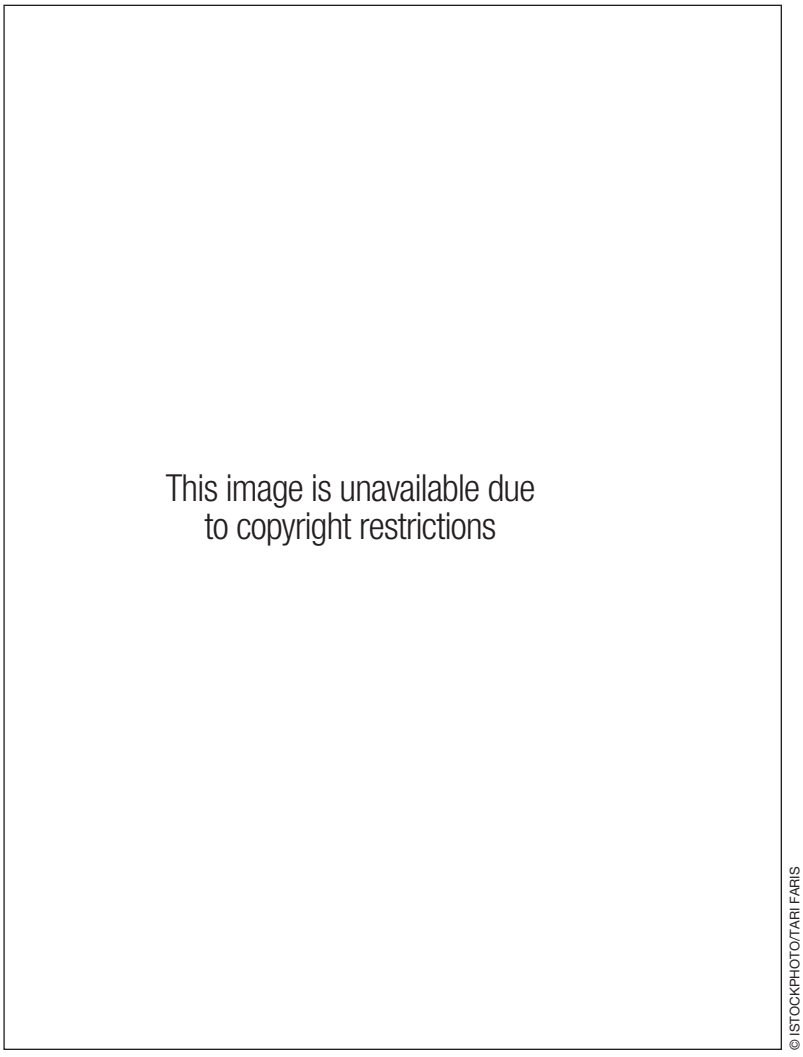
Infants have difficulty 'turning off' crying because of their immature ability to dampen sensory signals and inhibit distressed behaviour. An 8-month-old infant can be distracted from his or her crying or can self-soothe in a way that a 2-month-old cannot. The development of self-regulation and adaptive coping is dependent on the infant receiving appropriate responses from their carer.[7]

This is not to say that parents are responsible for their infant's unsoothable crying. Information for parents sometimes implies that they should be able to interpret every cry and settle every bout of crying. However, some nonresponsive crying is normal, particularly for babies in the upper-quartile range of time spent fussing or crying. Some infants may be fussy in spite of sensitive responsive parenting. In a community sample of 530 infants in the UK, below-optimum maternal sensitivity or affection was associated with an overall moderate increase in crying in infants at 6 weeks of age, but most mothers of persistent criers showed optimum sensitivity and affection. Mothers of persistent criers spent more time interacting with and physically stimulating their babies but by 5 months of age, when infant crying declined, no group differences were seen in maternal sensitivity, affection and intrusiveness.[8]

The total amount of time an infant spends in responsive fussing is influenced by characteristics of the infant and the carer's response, and there is debate about the best way to care for an infant. It is said that infants cry less in societies where the infant is traditionally held for most of the day and is allowed to breastfeed as desired, but robust data supporting this are lacking. However, factors such as the speed of parental response to the infant, the amount of time the infant is carried and responsive feeding patterns do affect infant behaviour (see the box on page 33).

Becoming familiar with the inherent pattern of crying and learning to interpret a baby's cries is more difficult if parents believe that their infant is in pain or has an underlying serious medical problem, and/or if they are overly anxious or experiencing postnatal depression. The duration of infant crying and fussing is longer in mothers who are distressed.[10] Excessive crying from their infants is more likely to be reported by:

- women who experienced psychomotor stress or depressive symptoms during the pregnancy or pregnancy-related anxiety or who are experiencing parenting stress or emotional problems
- women whose partners are dissatisfied with the sexual relationship
- parents who report experiencing negative feelings during the birth.[11,12]



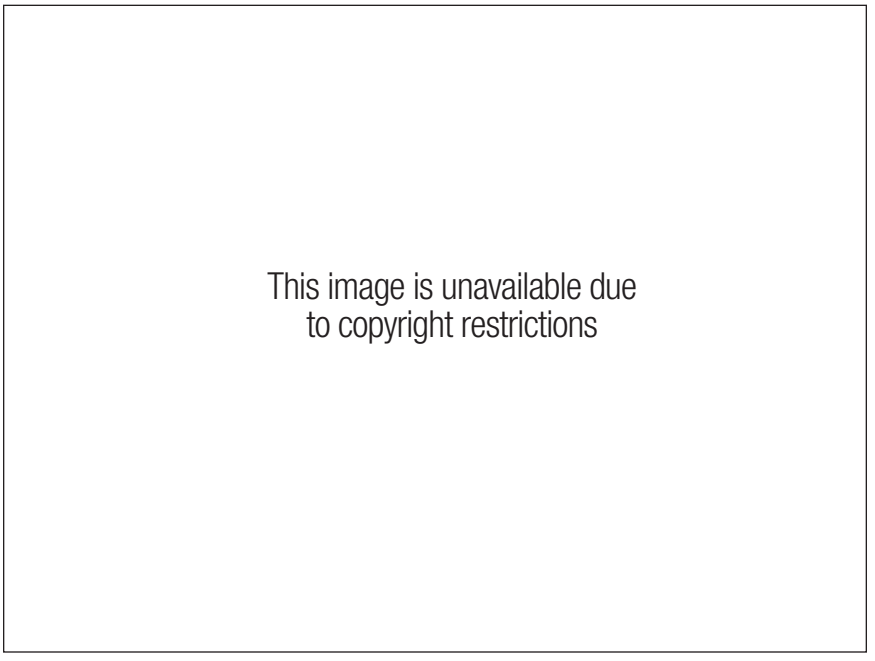


Figure 1. The temporal pattern of healthy crying in the first three months of life.
Adapted from Brazelton TB. Crying in infancy. Pediatr 1962; 29: 579-588.[2]

Causes of unsettledness

Theories as to the cause of fussing or crying behaviour abound but supporting evidence is scant.

Dietary factors

Breastfeeding mothers have long reported that they feel some foods in their diet upset their infant. A study has assessed the components of the maternal diet in relation to maternal recall of specific symptoms of colic in their infant in the preceding week. The results showed a significant relation between colicky symptoms and maternal intake of cruciferous vegetables such as cabbage and broccoli, cow's milk, onion or chocolate during breastfeeding.[13] Studies of allergy as a potential cause of unsettled behaviour are conflicting and have design problems. However, a small subset of bottle-fed infants have been shown to benefit from a trial of a hydrolysed formula.

Health professionals need to bear in mind Article 7.4 of the *International Code of Marketing of Breastmilk Substitutes* that states: 'Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children or members of their families'.[14] A sample is insufficient to conduct a trial of formula substitution, as feeding for one to three weeks is necessary. The *International Code of Marketing of Breastmilk Substitutes* and its subsequent resolutions are a joint WHO/UNICEF initiative whose aim is to protect the nutritional wellbeing of all infants. Australia was one of the first countries to sign the WHO code, which was adopted by the World Health Assembly in 1981.

For breastfed infants, results of restricting the mother to a hypoallergenic diet are conflicting. As for the formula studies, they were poorly designed with only small sample sizes, too short an observation period and lack of blinding.

Gastrointestinal causes

Unsettled behaviour is often attributed to gastro-oesophageal reflux or 'silent reflux' if regurgitation or vomiting are not present. Gastro-oesophageal reflux is considered normal in asymptomatic infants less than 3 months old and, unlike the pattern of crying, increases in frequency after that. Reflux is more common when the infant is awake or during periods of quiet sleep.[15] Behaviours associated with 'colic' and 'wind' are also likely to occur in these states. Orenstein was unable to show a positive temporal relation between crying and reflux as monitored by a pH probe.[16] Heine and colleagues reviewed 70 infants admitted with irritability ascribed to gastro-oesophageal reflux and showed that pathological reflux was significantly less common in infants less than 3 months old (4.2% *v.* 21.7%).[17] No cases of silent pathological reflux were found and they concluded that it is an unlikely cause of infant irritability under the age of 3 months.

Lactose intolerance with subsequent recommendations of dietary change is another common diagnosis in unsettled infants. Primary lactose intolerance presenting in an infant less than 3 months old is rare. Studies of the effect of decreasing the lactose intake of breastfed[18] and formula-fed infants[19] with unsettled behaviour and high breath hydrogen levels have not shown any positive effect on infant behaviour.

Reassurance, empathy, support and time-out (REST)[20] and parental counselling about effective responses to crying have been shown to decrease fuss or cry time compared with a comparison group of 'routine care'.[21] In one case-controlled trial, parental counselling was more effective than dietary changes in reducing crying.[22]

Assessment

The flowchart on page 34 outlines the steps to take when assessing an unsettled infant.

Fussing history

In the assessment of an unsettled infant a fussing history should be taken, asking parents about the following.

What is the pattern of your baby's crying or fussing?

- **Number of minutes of fussing per day:** does this fall into the upper-quartile or normal range (see Figure 1)?
- **Age of onset (adjusted for prematurity):** the parent's first response may be 'from birth', but this needs to be explored as unsettled behaviour typically starts at about 2 weeks of age (adjusted for prematurity)
- **Time course:** unsettled behaviour typically peaks at about 6 to 8 weeks of age
- **Diurnal rhythm:** typically crying is exacerbated in the evening
- **Day-to-day variation:** typically about 50%, meaning that a baby may cry twice as much one day as the next.

What have you found your baby best responds to?

Does your infant respond to your voice, being rocked or carried, white noise (such as the washing machine running), not wearing a nappy, being swaddled, riding in the car or walking in the pram?

What have you noticed overstimulates your baby?

Do days out, seeing visitors or Dad's stimulating behaviour when he comes home overstimulate your infant?

Is your baby fussing mainly with feeds?

If the baby is fussing mainly with feeds, a full feeding history should be taken.

- **Does the baby fuss before attachment?** Sometimes a baby will temporarily refuse the breast, but if he or she is otherwise well you can afford to offer the breast more frequently and express for comfort if needed; usually the baby will come back to it if not offered a bottle.
- **Does the baby fuss during the feed?** The baby may have an inco-ordinate suck, fail to make an adequate seal or have nasal obstruction. A careful developmental history and naso-oropharyngeal examination is required in such cases.
- **Does the baby refuse to continue feeding?** Some babies are very efficient feeders and don't need to feed for long. Others appear unsatisfied and a full breast-feeding assessment is needed.[23]

Types of unsettledness

When assessing an unsettled infant consider if the cry/fuss pattern fits the normal developmental pattern and falls within the normal range. Note the chronological pattern, day-to-day variance and diurnal pattern of the unsettledness to assign the infant to one of the following groups.

- **Infants whose crying or fussing lies outside the normal range.** Estimates suggest that fewer than 5% of infants presented to a health professional will fall into this category,[24] but it is the group that causes parents most concern as they fear the infant is crying because of a physical problem. The list of conditions that can cause unsettled behaviour covers the breadth of paediatric medicine.[25] If an infant is found to have an abnormal crying pattern a careful history, physical examination and directed investigations are necessary to determine the cause.
- **Infants whose crying or fussing lies in the upper quartile of the normal range.** Infants who fall in the upper quartile of normal behaviour are usually hyperalert. The parents can be assisted

The effect of proximal care

Researchers from Denmark, the USA and the UK studied the effect on infants of proximal care, which they defined as parenting that involved holding infants for 80% of the time or longer between 8 am and 8 pm (shared between caregivers as preferred), frequent breastfeeding and rapid response to infant cries.[9] They compared a group of 57 infants receiving proximal care with a group of infants from Copenhagen and another group from London, both of which did not receive proximal care. The proximal-care group:

- breastfed their infants more often (14 *v*. 12 *v*. 11 feeds a day for the proximal-care group, Copenhagen group and London group, respectively; $p<0.001$)
- fully breastfed for longer (85% *v*. 70% *v*. 37% at 12 weeks; $p<0.001$)
- spent more time holding their infant (16 *v*. 9.7 *v*. 8.5 hours a day; $p<0.001$)
- left the infant without contact when they fussed and cried for less time (10 *v*. 15 *v*. 38 minutes a day; $p<0.001$)
- usually slept with the infant for the whole night (70% *v*. 16% *v*. 9% at 12 weeks; $p<0.001$).

Infants from London were predominantly put to sleep in cots at night, while parents from Copenhagen used the cot and also took the infant into their bed for part of the night. There were no differences between the groups in the mean amount of unsoothable crying at any age. Up to 47% of infants experienced unsoothable crying, with the highest number reported at 5 weeks of age. Infants from London fussed and cried about 50% more per 24 hours than those from Copenhagen and those receiving proximal care at both 10 days and 5 weeks of age. The amount of fussing and crying decreased at 12 weeks of age in each group but remained higher in infants from London.

The proximal care form of infant parenting was associated with parental reports of more frequent waking at night and crying at 12 weeks of age than seen in the Copenhagen group. So the intermediate pattern of care used by parents from Copenhagen was as effective as proximal care in minimising early crying and more effective than proximal care in helping infants to sleep through the night at 12 weeks of age. The parents from Copenhagen met current recommendations for reducing the risk of SIDS by placing their infants to sleep in cots during part of the night.

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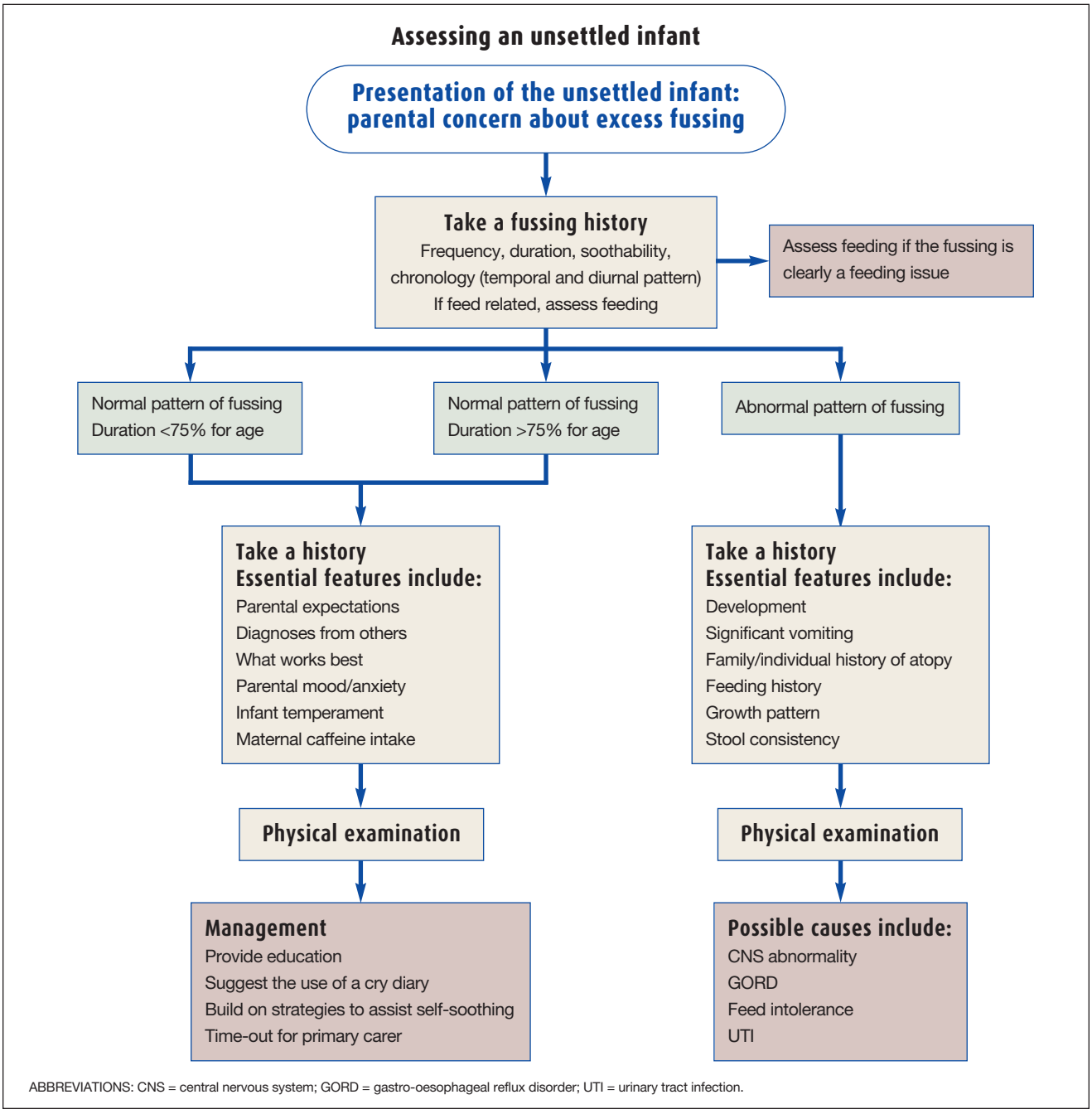

ABBREVIATIONS: CNS = central nervous system; GORD = gastro-oesophageal reflux disorder; UTI = urinary tract infection.

in assessing what soothes and what overstimulates their child, and can be guided in developing management patterns to minimise the infant's distressed behaviour.

- **Infants whose crying or fussing lies in the normal range but distresses the parents.**

Parents of an infant whose pattern of distress falls within the normal range need help and support in understanding the normal pattern of crying and assistance in responding to their infant's unsettledness.

Infants whose fussing falls in the upper quartile of the normal range form the bulk of those presenting to health professionals with excessive fussing or crying. There is a strong association with parental postnatal distress, and assessment for anxiety and parental emotional status should be part of the clinical assessment.

The parents may have beliefs about the cause of their infants behaviour that they do not share with their GP. Sometimes this is because it has been made by an alternative health practitioner and they think their doctor may not approve. It is important to elicit what the parents believe is the cause of the crying and to address this fully. Parents are more likely to interpret an infant cry as pain or hunger than to consider other options. Some common diagnoses of unsettled behaviour made include:

- colic
- 'wind'
- not enough milk
- lactose intolerance
- gastro-oesophageal reflux
- food intolerance or allergy.

In most cases there is no evidence to support these diagnoses as being causal of excessive crying, and 'medicalising' the problem may be detrimental in the long term.[26]

The essential history

Parental expectations

Understand how the parents expect their child to behave. This will guide you when it comes to explanations of the normal fuss/cry pattern and the expected changes with time that allow the carers to frame the baby's behaviour within the normal spectrum. Parents need to know that bouts of unsoothable crying are normal in the first three months of life and are not due to parenting practices. Bouts of unsoothable crying peak at about 6 weeks of age and start to decrease after that.

Diagnoses from others

It is important to establish what the crying means to the carers. They may have been given explanations such as the mother's milk is insufficient or too weak. Two examples of explanations I have been told by parents are: 'The baby is holding its head to one side because it has a headache' (advice from an alternative practitioner; the baby had a sternomastoid tumour); and the 'baby doesn't like me' from a women who believed that her own life-long poor relationship with her mother was because her mother did not like her because of her crying, which was later attributed to an allergy to her mother's milk. Without eliciting and addressing these concerns, management is likely to be ineffective.

What works best?

If simply asked 'what settles your child?', parents may respond 'nothing'. Asking 'what works best?' allows them to develop some options. It is important not to imply that parents should understand and be

Maternal caffeine intake

- Caffeine peaks in human milk 60 to 120 minutes after ingestion
- Infants receive about 0.1% of the maternal dose of caffeine
- Occasional irritability may occur in infants after caffeine intake
- The half life of caffeine in an infant is 97.5 hours in a neonate and 2.6 hours in a 6-month-old infant

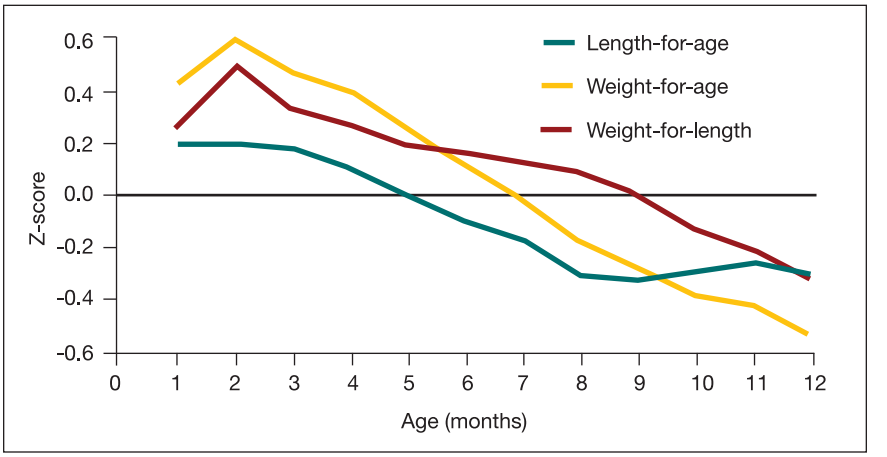

Figure 2. Mean z scores of infants breastfed for ⩾12 months relative to the NCHS reference. Healthy breastfed infants appear to 'fail to thrive' in the second 6 months when plotted on the NCHS charts.
Adapted from Working Group on Infant Growth. An evaluation of infant growth. Geneva: World Health organization; 1994.[28]

able to stop every bout of crying. Advice sheets for parents about responding to their babies crying often have lists of 'try this' followed by 'try that' with an implication that if they work down the list they will eventually find a cause and stop the crying. This diversional therapy is likely to be effective in the short term as it gives parents confidence that they are competent and doing something, lowering parental anxiety and having a high placebo effect. However, it is important to consider the long-term effects of this approach. Implying that there is something wrong with the baby by recommending strategies such as complementary feeds or formula changes may be associated with long-term changes in parental perceptions of the wellness and vulnerability of their infant.

Parental mood/anxiety

Measurement of the Edinburgh postnatal depression score is helpful in screening for maternal depression.

Infant temperament

Infants who have 'high needs' in the first two weeks of life are likely to continue to do so at 6 to 8 weeks of age but this will improve with time.

Maternal caffeine intake

Caffeine has a longer half life in an infant and a breastfeeding mother with a high caffeine intake may exacerbate her infant's periods of fussing or crying (see the box on this page).

Medical history

Crying that is not part of the normal spectrum may be detected by its unusual pattern and/or other indicators. A full developmental, feeding, atopic and general health history is needed. For example:

Management of crying or fussing in the absence of a causal medical problem

- Fussing or crying is less often perceived as a problem to parents when they are asked to keep cry diaries than when asked to recall details of their infants crying.[29] So asking the parents to keep a cry diary is helpful.
- Educate the parents about the likely development from here. Explain the natural spontaneous improvement that occurs at about 6 to 8 weeks of age. This may explain the wonder cure that other parents have reported to them. 'Nothing worked until we tried …'
- Ensure that parents know that some inconsolable crying is normal, peaks at about 6 weeks of age and is inherently part of the baby's development. It is not the result of anything they are or are not doing.
- Address any issues parents may have with diagnoses previously offered.
- Explore any treatments currently being used and ensure their long-term safety.
- Work with parents to enhance their confidence in their parentcraft skills and develop what they have found works for their baby.
- Address time out for parents and strategies to use if their infant's behaviour is too stressful. Who is available for support?
- Explore strategies used before when the baby's crying has been stressful to identify behaviours that put the infant at risk. About 3% of parents admit to smothering, shaking or slapping their crying child.[30] If abuse is suspected, contact child protection authorities and follow mandatory reporting procedures.
- Reassure the parents that weaning, adding complementary formula feeds or starting solids is not likely to have a genuine positive effect.
- Address any anxiety disorder/depression in the parents.
- Ensure ongoing support and arrange review if needed.
- Reassure parents that they are doing a good job with a challenging infant. Others who have more placid babies will find it a lot easier – it is not due to better parenting.

- babies in whom signs of cerebral palsy become evident have different cry histories
- babies who have gastro-oesophageal reflux disease have significant vomiting, blood in the vomit or poor growth
- babies who may respond to elimination diets in their mother or to a change of formula if they are bottle fed more often have a history of atopy in themselves or the family
- blood in the babies stool may suggest allergic colitis.

Physical examination

A careful, full physical examination is essential to identify those few infants who have an underlying disorder or to reassure parents that their baby is normal. It is important to plot babies on the WHO standard growth charts,[27] not other reference charts, to avoid spurious concerns about failure to thrive (Figure 2). Compared with the National Center for Health Statistics or the Centers for Disease Control reference charts, babies on the WHO growth standard charts are bigger at birth (attributed to better maternal health and obstetric care) and shorter and leaner from about 6 months of age. Healthy breastfed babies plotted on reference charts may be incorrectly thought to be failing to thrive from about 6 months of age.

Taking a careful history and physical examination is an important part of the therapy. The rate of return in terms of physical diagnoses is low but the parents need to be confident that medical problems have been excluded. Investigations are not routinely needed but dictated by findings on the history or examination. The box on page 38 summarises some key points in the management of unsettled infants in the absence of a causal medical problem. Some useful resources are given in the box on page 42.

Interventions to settle the infant

Because of the temporal pattern of infant crying there are few well-designed intervention studies. Many studies can be discounted because of flaws in their methods. The placebo effect in open trials is very convincing and so double-blind, placebo-controlled, crossover trials are necessary. Participants cannot be recruited until excess fussing becomes evident in the first two to four weeks of an infant's life. The baseline crying pattern needs to be documented and parentcraft support given to eliminate those that resolve with simple interventions such as supporting a mother in her parenting skills[31,32] or management of maternal distress or depression. So,

Useful resources

Parent resources

- UpToDate is an online resource for patients to learn more about a medical condition. www.uptodate.com/patients
- Crying babies factsheet. www.sch.edu.au/health/factsheets/joint/?cryj.htm
- McVeagh P, Reed E. Kids Food Health First Year. Sydney: Finch Publishing; 2001.

Review articles

- Wade S. Infantile colic. Clin Evid 2006; 15: 439-447.
- Herman M, Le A. The crying infant. Emerg Med Clin North Am 2007; 25: 1137-1159, vii.

Table. Efficacy of various interventions offered to parents of unsettled infants*

- Likely to be beneficial — Whey hydrolysate milk formula in bottle-fed infants
- Likely to be beneficial but with unacceptable risks — Anticholinergic drugs such as dicyclomine hydrochloride (not available in Australia)
- Unknown effectiveness — Soy-based milk formula, casein hydrolysate milk formula, low-lactose milk formula, sucrose solution, herbal tea, reduced stimulation, car ride simulation, cranial osteopathy, focused counselling, infant massage, spinal manipulation, low-allergen diet by breastfeeding mothers
- Unlikely to be beneficial — Lactase, simethicone, increased carrying

*Adapted from Kilgour T, Wade S. Infantile colic. Clin Evid 2005; 13: 362-372.[34]

intervention is likely to start at the peak of crying behaviour and be followed by natural resolution. An adequate wash-out period is required between treatment arms and sufficient days of observation to allow for day-to-day variation in crying duration. By this time the problem has usually spontaneously resolved.

The numerous interventions suggested to parents all appear to work in about one-third of infants. A summary of the current level of evidence for these interventions is given in the Table.[33, 34]

Parents often give medication to their unsettled babies. At the Tresillian Family Care Centre in Willoughby, Sydney, 70% of infants under 3 months of age admitted with unsettled behaviour have previously received at least one type of medication (unpublished observations). The only medication that has been shown to be effective is dicyclomine hydrochloride but this has been withdrawn because of its side effects.[35] In a prospective double-blind noncrossover study, a herbal tea preparation of chamomile, vervain, licorice, fennel and balm-milk was significantly more effective in eliminating colic and improving a colic score than placebo.[36] The description of the mechanism of action of the mixture, however, was worryingly similar to that of dicyclomine. In addition, the infants were drinking a significant amount of tea, which may have decreased their milk intake.

Summary

When an infant under 3 months of age presents with fussing or crying behaviour a comprehensive history to establish the crying pattern, growth velocity and associated symptoms followed by a thorough physical examination are the first essential steps. Parents convinced that their child is in severe physical pain are unlikely to be reassured without this.

Where the infant's crying falls in the normal pattern, the infant is thriving and history and examination are unremarkable, there are unlikely to be any significant organic problems in the infant. A history to establish the mother's level of distress is then important. Significant depression occurs in up to 30% of mothers and in more than 60% of mothers presenting to a residential care service with infant management problems.

Normalisation of the behaviour and giving the parents strategies for responding to their infant's distress are effective for many parents. For those infants who fulfil the criteria outlined above but whose parents are still concerned, any intervention will have a high, temporary placebo effect. For some, changing the feed protein may be effective but in the clinical situation this is unlikely to be distinguishable from a placebo response. Choosing the least noxious intervention is important in this self-limiting condition. MT

A list of references is available on request to the editorial office.

COMPETING INTERESTS: Dr McVeagh is the Royal Australasian College of Physicians' representative on the Administrative Body for the Baby Friendly Hospital Initiative in New South Wales. From 1998 to 2002 Dr McVeagh was the Community Representative appointed by the Commonwealth Government to the Advisory Panel on the Marketing in Australia of Infant Formula.

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