

Professional Notes:

Reflections on the Hawthorne Effect

'In Praise of the Hawthorne Effect', Editorial, Dixon, Can Fam Physician (April 1989) 35:703-704.

The Hawthorne effect (the effect of participation) is the phenomenon whereby mere participation in a trial means that patients experience better results, regardless of the treatment, simply because they are getting unusual and gratifying attention. (The name comes from a study at the Hawthorne plant at Western Electric in the U.S. in the 1930s. It was found that improved lighting improved the

productivity of workers. Someone had a bright idea – the researchers tried reducing lighting and this also improved productivity. It was the attention that was important, not the light).

'Good' research is designed in such a way that the Hawthorne effect, and a host of other confounding biases, are eliminated or minimized. Tony Dixon MD, Editor, Canadian Family Physician makes this complaint:

"I entirely understand the concern with neatness, but I confess a strong attachment to the Hawthorne effect, as I reckon it is the basis of a good deal of my practice activity ... Rather than being an irritating side effect, the Hawthorne effect seems to be a central feature of family medicine."

The trouble with controlled trials and concentrating on what is measurable, he says, is that "we are left with the trivial." The essence of primary practice is extracted from the trial, which therefore becomes irrelevant.

THE CHIROPRACTIC REPORT

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INFANTILE COLIC - a new study from Denmark

A. Introduction

1. 'Infantile colic' is a term used to describe persistent, often violent, crying for no apparent reason in otherwise healthy and thriving young infants. The distressed behaviour is believed to be a reaction to pain. It is different from normal crying because distress does not stop when the infant's physiological needs are met.

Colic begins at 1-4 weeks of age and usually ends spontaneously at 3-4 months of age. In the meantime, especially in moderate to severe cases which may involve uncontrollable crying for many hours by day and night every day, it is destructive to both infant and family and is a cause of parental violence to infants. ^{1,2,3}

2. Because the source of the irritability and pain in infantile colic has been and remains unknown, because onset follows the trauma of birth and change to a weight-bearing environment, and because they have found a high incidence of abnormality in cervical and thoracic spinal joint function in colicky infants, chiropractors have postulated that a significant cause of infantile colic may be spinal dysfunction or subluxation (see para 12).

For many years there have been anecdotal reports of excellent results following palpation and manual correction of spinal joint dysfunction using appropriate light adjustive techniques, and in recent years there have been similar reports from medical specialists in Europe. ^{4,5} In 1985 Nilsson DC, MD, who has both chiropractic and medical qualifications and is currently Academic Dean, Anglo-European College of Chiropractic, Bournemouth, England, reported good results with chiropractic management of infantile colic in 90% of infants in a retrospective questionnaire study. ⁶

- 3. These results have now been confirmed in a well-designed prospective, multi-centre study by Klougart DC, Nilsson DC, MD and Jacobson DC published in the August 1989 issue of the Journal of Manipulative and Physiological Therapeutics (JMPT).⁷ The study:
- Had a population of 316 infants, with median age of 5.7 weeks at first examination and treatment.
- Comprised subjects with moderate to severe colic (average of 5.2 hours of persistent crying per day).

- Reported successful results in 94% of cases following a 2 week treatment period.
- Concluded "the results of this study suggest that spinal manipulation of the vertebral column in infants with infantile colic constitutes an effective treatment of the condition."

51% of the infants had had prior unsuccessful treatment, usually drug therapy (83%).

4. In this issue the study is reviewed in some detail. There is then comment on the much greater acceptance in health science today of prospective studies of this nature – as opposed to fully controlled, randomized trials. During the past year there have been calls from the New England Journal of Medicine⁸ and other prominent research journals^{9,10} for more good prospective studies, emphasizing *qualitative* as well as *quantitative* results of treatment.

B. Danish Study

General Design

5. 73 chiropractors from 50 clinics in Denmark participated in this prospective multi-centre study, coordinated by the Danish Chiropractic Association.

During the three month period April to June 1985, 569 infants presented as patients at participating clinics. 316 fulfilled the criteria for inclusion (see para 7), and formed the study population.

- 6. All participating clinicians attended meetings for thorough instruction on study design and procedures which included:
- a) A structured initial interview with standard questions and resulting patient profile covering items such as pregnancy, birth, feeding, thriving, the colic and its manifestations (gastrointestinal and motoric), previous treatment of the colic, previous illness and treatment.
- b) A standard diary kept by mothers for 28 days and recording feeding, awake and sleep periods, and symptoms (stools, colic periods, etc). The investigators refer to earlier research in which this diary method was developed and accepted as reliable.
- c) Structured interviews with mothers by chiropractors 1, 2 and 4 weeks after commencement of treatment, yielding overall subjective evaluation by mothers of intensity of colicky crying, which enlarged upon the objective data in the diaries.

Inclusion Criteria

- 7. Criteria for inclusion in the trial were:
- a) Parental consent.
- b) Age between 2 and 52 weeks. (Median age at beginning of treatment was in fact 5.7 weeks).
- c) No symptoms suggestive of any other disease apart from the colic.
- d) At least one violent crying spell lasting a minimum 1.5 hours during 5 of the 7 preceding days, and normal behaviour outside colicky periods.
- e) No previous illness apart from colic.
- f) Weight gain of at least 150 grams per week.
- g) Behaviour during colic including motoric unrest, frequent flexing of the knees towards the abdomen and or backward bending of the head and trunk.
- h) Presence, upon chiropractic examination, of spinal functional disturbance.
- i) During colic inability to be comforted by various normal means, including cradling, change of diaper, offer of food or other comfort. 253 of 569 infants failed to meet these inclusion criteria, leaving 316 in the study.

Spinal Analysis and Treatment

- 8. Standard evaluation of joint function was performed as follows:
- Palpation by hand of ranges of movement (motion) of the joints of the spine and pelvis, at initial visit and each consultation thereafter.
- Recording of dysfunctions (subluxations) found, and then joints treated.
- 9. Treatment was limited to spinal manual therapy to correct joint dysfunction or subluxation, but actual technique was left to the discretion of each individual chiropractor. As the investigators report, chiropractic treatment of infants follows the same principles as for adults, but with important modifications. Force is greatly decreased, the contact is usually one finger alone, and the adjustive thrust - if performed at all - is very modest. The manipulative 'crack' from the release of gas within the joint which usually marks the joint manipulation of adults is very rarely, if ever, heard. Treatment is no more trouble to the infant than basic physical examination.

Results

- 10. Findings of the study are:
- a) Infants in the study had a median age of 2 weeks at commencement of colic, a median age of 5.7 weeks at beginning of treatment. (See Fig. 1).
- b) Prior to treatment the average daily length of time with colic was 5.2 hours, average number of episodes per day 2.5.

There was a "dramatic reduction" in hours with colic occurring on the first day of treatment – reduced by more than half to 2.5 hours. There was then a pattern of continuous reduction to an average of 0.65 hours per day on day 14. (See Fig. 2).

Average colic episodes per day were 2.5 at outset, 1.3 after one week, and 0.9 after two weeks.

- c) At 2 weeks, following an average number of 3 treatments, there was a success rate of 94% (colic stopped 60%, improved 34%). Of the balance of 6%, there was no significant change in 4%, and 2% were worse. On assessment at 4 weeks improvement was maintained.
- d) With respect to spinal level of treatment, 94% of infants were treated at the two upper cervical joints, 53% in that area alone and 41% also in the thoracic spine (generally T4/5 to T8/9).

The 6% not treated in the upper cervical region were treated in one or more regions between the lower cervical spine and sacroiliac joints.

- 11. Comments on these results are:
- a) The results are especially promising since no adverse side effects were reported.
- b) A brief time span of 14 days was chosen so that the influence of spontaneous resolution of colic symptoms could properly be disregarded. (Average age of the infants at 2 week assessment in the study was only 7.7 weeks). There was a dramatic then consistent correlation between course of treatment and recovery. Accordingly this study represents good evidence that standard chiropractic treatment constitutes an effective treatment of infantile colic.
- c) The study's main limitation is that it did not compare two groups of infants those receiving active treatment and those receiving a sham or placebo treatment as in a randomized, controlled, double-blind trial. The investigators report that they are now proceeding with the design of such a

trial, which will involve two clinics, recruitment of patients by health visitors, random allocation of infants to one of three groups (an untreated control group, group

continued on page 5.

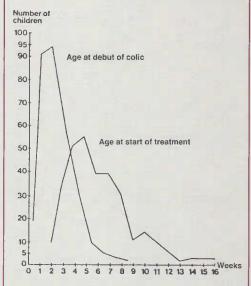


Figure 1. Distribution of the population with regard to age in weeks at onset of colic symptoms and age in weeks when chiropractic treatment was instituted.

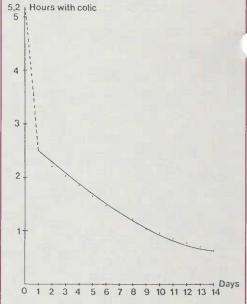


Figure 2. Average daily length of colic from days 1-14 based on 256 complete diary recordings for the period. Day 1 = 2.5 hr, day 14 = 0.65 hr. The average time with colic on day 14 represents a 75% reduction in colic crying time compared to day 1.

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WORLD FEDERATION OF CHIROPRACTIC

Background

All major health professions, and most medical specialties, have world organizations representing national members in the development of international health policy, particularly in relation to the World Health Organization (WHO) and its various agencies. As the world has become smaller, and national health care decisions on manpower, funding, and many other issues are increasingly derived from international policy conferences, the need for representation has become stronger.

At a meeting of presidents of national chiropractic associations convened by the European Chiropractors Union in London, England in October 1987 a Committee was established to consult widely - with all countries known to have chiropractors in practice and with existing world federations of health professionals - and prepare a draft constitution for a truly representative world chiropractic organization. Such a constitution was prepared during the next 12 months and formally adopted at a meeting in Sydney Australia in October 1988 at which the World Federation of Chiropractic (WFC) was constituted.

Structure

- Voting members are national associations of chiropractors (generally one per country, but for historical reasons two in each of Australia (ACA and UCA) and the United States (ACA and ICA)). All eligible national associations but one (Panama) have applied for membership, and paid dues based on the number of voting DC members in the association.
- · Authority for all policy and other major decisions is vested in member national associations in general meeting - the Assembly – which takes place in a different country every two years. The next Assembly will be in Toronto, Canada May 1-5 1991. Larger associations receive a weighted vote, but small associations have the strongest proportional representation and no country or world region has the possibility of a majority vote in Assembly.
- The continuing business of the WFC is conducted by a Council, elected by national association according to 7 world regions modelled on those of the WHO - Africa, Asia, Eastern Mediterranean, Europe, Latin America, North America and the Pacific.

In the Council, as in the Assembly, regions with more chiropractors have a weighted vote, but no one region can acquire a majority vote, or the power of veto. The North American region has members representing Canada and both the ACA and ICA in the United States. The Council, which meets at least once annually, has its next meeting in Geneva, Switzerland in May 1990 at the time of the WHO annual meeting, the World Health Assembly.

- The Council, elected by member associations, appoints a President, Vice-President and Secretary-Treasurer. They comprise an Executive Committee which supervises the day-to- day business of the WFC.
- The WFC's secretariat (office) is in Toronto, under the direction of Secretary-General Mr. David Chapman-Smith LL.B (Hons), FICC (Hon), an attorney who served as Chairman of the committee that prepared the WFC's constitution.
- Other categories of non-voting membership (e.g. for specialized chiropractic organizations active at national and international levels) will be considered at the Council's next meeting. There is unlikely to be a category for individual chiropractors, whose access to the WFC in terms of membership, services, and support through their national associations.

The formal goals of the WFC, found in Article 2 of the constitution are to serve humanity by:

- · Encouraging improved standards of chiropractic education and practice in order to provide the highest quality of service to the community.
- · Cooperating with appropriate national or international organizations to provide information, counsel and assistance in the fields of chiropractic and world health.
- Encouraging research and the exchange of information with respect to chiropractic, in part through regular international congresses of chiropractic.
- · Assisting in developing an informed public opinion among all peoples with respect to chiropractic.

These goals reflect a founding principle of the WFC, that there be no interference in the domestic chiropractic affairs of any

MEMBER ASSOCIATIONS

(Ratification Pending)

Australia (ACA and UCA)

Belgium Mexico Brazil Namibia Netherlands Canada New Zealand Chile Norway Cyprus Denmark Peru Philippines Ecuador

Finland Singapore France Spain

South Africa Sweden Guam Hong Kong Switzerland

Taiwan Iran Ireland

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Pacific:

Dr. John Sweaney (Executive Director, AustCA)

country unless expressly requested by the chiropractic association in that country.

Early Actions Taken

- Appointment of an appropriately qualified Research Council, to plan the WFC's first Scientific Congress in Toronto May 1-5, 1991 and to assist in bringing greater unity worldwide between chiropractic leaders in education, research, and professional associations.
- Preparation of an article on chiropractic to appear in the April 1990 issue of *World Health*, a WHO magazine published in eight languages and distributed to health agencies worldwide.
- Commencement of databank of current information on chiropractic associations, addresses and developments internationally.
- Assisting the introduction of chiropractic services in countries such as Fiji, Kuwait and Taiwan.
- Responding to requests from the chiropractic profession for assistance in meeting legal and legislative challenges in various countries, including Chile, Cyprus,

France, Guam, Jordan and Kuwait.

- Assisting students from Third World countries to enter accredited chiropractic colleges, and assisting new educational initiatives in Mexico and South Africa, including scholarship assistance especially for black, Asian and other disadvantaged students at Africa's first chiropractic college, the multi-racial Technikon Natal program in Durban, South Africa.
- Coordinating and documenting international chiropractic aid projects by organizations such as the ICA, Renaissance International, the Christian Chiropractors' Association, and various state associations in the U.S.A. supporting chiropractors in countries such as Brazil, Colombia, Cuba, India and Zimbabwe.

(If you are engaged in any international chiropractic aid work, or know of chiropractors in other countries of whom the WFC may be unaware, please write with details to: Mr. D. Chapman-Smith, Secretary-General, World Federation of Chiropractic, P.O. Box 244, Station "S", Toronto, Ontario, M5M 4L7, Canada.)

Assembly and Congress - Toronto May 1-5, 1991

Following its Council meeting in September the World Federation of Chiropractic (WFC) has announced that it will be holding its next Assembly (general membership meeting) and Scientific Congress in Toronto, Canada May 1-5, 1991 at the historic Royal York Hotel.

The Congress, to be held in conjunction with the 1991 Spring Symposium of the American Back Society, will feature leading researchers and clinicians from chiropractic and related disciplines worldwide. Program details, currently being developed by the WFC's Research Council chaired by Dr. Scott Haldeman, DC, MD, Ph.D, chiropractor and consulting neurologist of Santa Ana, CA, will be available following the next WFC Council meeting which will be held in Geneva May 8-10, 1990 at the time of the annual meetings of the World Health Organization.

WFC EXECUTIVE COMMITTEE



Executive Committee (WFC): (left to right) Dr. John Sweaney, Australia, Secretary-Treasurer; Dr. Gary Auerbach, United States, President; and Dr. Christoph Diem, Switzerland, Vice-President.

Gary Auerbach, DC, *President* Council member (1 of 5) for North America, (Palmer, 1975)

Dr. Auerbach's appointment recognizes his leading role as an ICA Director during the past 8 years in establishing international relations within the chiropractic profession and chiropractic representation at the World Health Organization.

He and the ICA were the architects of regional congresses in Venice, Italy (1982), Cancun, Mexico (1983), Seoul, Korea (1984) and Athens, Greece (1985) which led to publication of the FACTS Bulletin 'A Study of Chiropractic Worldwide' giving details of the chiropractic profession in each country. (A new third edition of this publication will be available from the ICA in January 1990).

Christoph Diem, DC, Vice-President Council member for Europe, (National, 1972)

Dr. Diem, who practises in Winterthur, Switzerland, is Vice- President of the Swiss Association of Chiropractors and President of the European Chiropractors' Union (ECU). Because of the diverse problems facing chiropractic in the European countries, ranging from full acceptance (e.g. Switzerland) to a continuing struggle for legislative recognition (e.g. France and Spain) and his long political experience Dr. Diem has become a highly respected leader in the profession.

John Sweaney, DC, Secretary-Treasurer Council member for Pacific, (Canadian Memorial, 1968).

Dr. Sweaney is a Past-President and currently Executive Director of the Australian Chiropractors' Association. He has led the Australian profession during its time of most rapid evolution – the period since the early 1970s in which there has been legislative recognition in every state, university affiliation and government funding for education at chiropractic colleges in Melbourne and Sydney, and major federal and state government inquiries endorsing chiropractic and recommending funding for chiropractic services. Also highly respected internationally for his experience and judgement.

RESEARCH COUNCIL

The WFC is privileged to have as Chairman of its Research Council Scott Haldeman, DC MD Ph.D, a chiropractor and consulting neurologist from Santa Ana, California. Dr. Haldeman, whose basic science doctorate is in neurophysiology, is widely published, President-Elect of the North American Spine Society, in heavy demand worldwide as a speaker, and is recognized internationally as one of the leading spinal researchers of his generation. He is Editor of the text 'Modern Developments in the Principles and Practice of Chiropractic' (Appleton Century Crofts, New York 1980), the second edition of which is near completion.

Other members of the Research Council are prominent researchers in their various countries:

- , Alan Breen, DC. Director of Research, Anglo-European College of Chiropractic, England
- David Cassidy, DC FCCS(C), M.Sc. of Saskatoon, Canada
- Lynton Giles, DC Ph.D., Director, Spinal Research Laboratory, Griffith University, Brisbane, Australia
- Reed Phillips DC DACBR Ph.D., Director of Research, Los Angeles College of Chiropractic, United States
- John Triano, MA DC, Director, Spinal Ergonomics Laboratory, National College of Chiropractic, Lombard IL.

Main Article: continued from page 2.

receiving chiropractic treatment according to palpation findings, and group receiving sham chiropractic treatment), and blind assessment.

How does manipulation work?

12. The report of the study does not consider the mechanisms by which chiropractic correction of spinal dysfunction relieves the symptoms of colic which, apart from presumed pain, frequently include a tense or distended abdomen, rumbling abdominal noises, and passing excess air.

No definite answer is yet known to the neurophysiologists and chiropractic, medical and osteopathic clinicians and researchers who have studied this question. Much more needs to be known about:

- · The source or sources of pain; and
- Somatoautonomic reflexes within the nervous system. (New technology for analysis of nerve activity developed during the past 15 years is producing a great deal of new evidence in this area generally, and in 'Modern Developments in the Principles and Practice of Chiropractic' Sato MD reviews recent evidence on the now "well known" somatogastric reflex in simple language, the influence of experimentally induced nerve activity on digestive function.)¹¹
- 13. Currently chiropractic science offers these explanations or hypotheses as to how correction of spinal joint dysfunction may help or remove the symptoms of infantile colic:
- a) In some cases referred pain from spinal joint dysfunction simulates and is mistaken for abdominal pain. (Some infants in the Danish study did *not* have a tense abdomen, rumbling noises, excessive air, or other gastrointestinal manifestations during 'colic'). Correction of the spinal problem, in this instance the real source of symptoms, brings relief.
- b) A relatively mild digestive disorder produces a reflex response in the nervous system that causes spasm of the paraspinal muscles and spinal joint dysfunction. Pain from this dysfunction takes the infant to a level of discomfort that produces persistent colicky crying. Correction of the spinal problem (secondary to the digestive disorder, but the primary source of pain) brings relief.
- c) Digestive dysfunction and discomfort may be secondary to spinal joint dysfunction. Reduced mobility in a spinal joint, and/or paraspinal muscle spasm, produces a reflex response in the nervous system. This causes sustained, altered neurophysiological effects in nerve pathways to the gastrointestinal system, aggravating or causing digestive dysfunction.

More specifically, the reflex response includes somatic afferent bombardment of dorsal horn cells in the spinal cord, chronic excitability of neurones at that level in the spine (called 'segmental facilitation' by researchers), evoked abnormal autonomic reflexes, and irritability and dysfunction of the internal systems regulated by the affected autonomic pathways. This explanation is known as the 'somatoautonomic reflex hypothesis'.

Leach DC¹² provides more detail on this and related hypotheses and reviews supporting evidence from chiropractic, medical and osteopathic research. Other valuable contributions in the general area of relations between spinal dysfunction and internal problems appear in the work of Kunert MD,¹³ Lewit MD,⁵ Korr Ph.D,¹⁴ and – with respect to infants – Gutmann MD.⁴)

14. A final point of interest from the Danish study is how widely chiropractic management of infantile colic is used in Denmark. In 1985 there were approximately 50,000 births in Denmark, and infantile colic is estimated to affect about 20%.

If the patient figures from those chiropractors participating in this study are extrapolated to the whole Danish profession it can be assumed, the investigators report, "that 20-40% of all infants in Denmark suffering from infantile colic are being treated by chiropractors."

C. Trials v Studies

15. The Danish 'study' is not a 'trial'. What is the difference, and does a 'study' afford reliable evidence?

The four common forms of clinical research, in descending order of scientific rigour are:

- a) Randomized Controlled Trial (RCT). A trial gives a defined treatment to one group of patients while a second control group receives a sham treatment or placebo. Patients do not know whether they are getting the real or placebo treatment (single blind) and the researchers measuring the results don't know which group the patient was in (double blind). A third group of patients can be added, receiving a second active treatment, and this allows the trial to compare not only effectiveness as against no treatment, but comparative effectiveness of two treatments. Other controlled trials just measure two alternative treatments. (However, these are subject to the criticism that all of the patients may have got well anyway there should have been a non-treatment, control group.)
- b) Descriptive Study. The next best method, this type of study looks at the response of a series of patients to a given treatment according to methods carefully worked out in advance i.e. it is a prospective study. However, there is no comparison with another treatment group or a placebo (control) group. (The Danish study falls into this category).
- c) Case Control Study. Similar to the descriptive study, but weaker in design because the study is commenced after treatment was given which means that fewer factors of bias are controlled and results are less reliable. The study is retrospective rather than prospective.
- d) Observational Study. Similar to the case control study except that there is no contact between the researchers and patients.

(For a more detailed analysis of these research methods, and comment on the strengths and weaknesses of RCTs, see the September 1987 issue of The Chiropractic Report. (Vol. 1 No. 6)).

- 16. Until recently it was blindly asserted by many that a full RCT was necessary for acceptable evidence of the effectiveness of a treatment. Problems with this stance include:
- A competent RCT is extremely costly and time-consuming. (Design of the current British trial comparing chiropractic and medical management of low-back pain commenced in 1979, the pilot trial was published in 1986, treatment in the main trial finished in March 1979, two year follow-up ends in 1991, and final results are unlikely to be published before 1993 a period of 14 years, and all at a cost in excess of \$500,000).
- To avoid this time and cost many researchers have worked with small populations of patients and compromised trial design (scientific credibility) and statistical power (ability of the trial to recognize true treatment effects).
- Best estimates are that 80% of all medical treatments and technologies have no such proof of effectiveness.¹⁵
- 17. Experience is now showing that good descriptive studies by competent researchers may have similar scientific weight to RCTs and are much more practical thus are often more valuable and to be preferred. Greenfield MD, in a recent editorial in the New England Journal of Medicine titled 'The State of Outcome Research: Are We on Target?' ¹³ concludes:

"An exclusive reliance on randomized controlled trials to provide definite information about effectiveness is not the answer. We cannot afford to conduct randomized controlled trials for every test, procedure, or medication in use. To do so would require far too many research resources and would not produce results soon enough."

He then argues in support of observational studies. He does so because in that issue of the NEJM, in a move that would have been controversial five years ago, such a study is being published.

He then comments at some length in support of the type of research outcome seen in the Danish study – *qualitative* outcomes ("... such as the reduction of symptoms, improvement in daily functioning, or improvement in the sense of well-being and ... quality of life") rather than *quantitative* (precise numbers, complete removal of symptoms).

18. Hurst MD in another recent editorial this time in the Journal of the American Medical Association, justifies publication of a new observational study in similar fashion, saying:

"Whereas many experts demand randomized trials to determine the value of a specific form of treatment, our Duke friends have emphasized that observational studies are also useful ... I, too, believe that excellent observational studies by superb clinical investigators can teach us all a great deal."

19. None of this means that the RCT is no longer important – it remains the gold standard and all major health disciplines, including chiropractic, continue research at that level. However it does mean that the Danish study represents valuable new evidence suggesting, as its authors report, that skilled manual detection and correction of spinal joint dysfunction in infants with infantile colic "constitutes an effective treatment of the condition."

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References

- 1 Illingworth RS (1985) 'Infantile Colic Revisited' Arch Dis Child 60:981-985.
- 2 Caffey J (1972) 'On the Theory and Practice of Shaking Infants' Am J Dis Child 124:161-69.
- 3 Frodi AM (1981) 'Contribution of Infant Characteristics to Child Abuse' Am J Ment Defic 85:341-49.
- 4 Gutmann, G (1987) 'Blocked Atlantal Nerve Syndrome in Babies and Infants', Manuelle Medizin 25:5-10.
- 5 Lewit K (1985) 'Manipulative Therapy in Rehabilitation of the Locomotor System', Butterworth and Co., London and Boston, 336-340.
- 6 Nilsson N (1985) 'Infantile Colic and Chiropractic, Eur J Chiro, 33:624-65.
- 7 Klougart N, Nilsson N and Jacobsen J (1989) 'Infantile Colic Treated by Chiropractors: A Prospective Study of 316 Cases', J Manipulative Physiol Ther, 12:281-288.
- 8 Greenfield S (1989) Eng L J Med 330(17):1142-1143.
- 9 Hurst JW (1989) 'Editorial: The Value of Coronary Bypass Surgery Compared with Medical Therapy', editorial 261(14):2118.
- $10\,\rm Dixon\,T\,(1989)$ 'In Praise of the Hawthome Effect' and 'The Philosophies of Family Medicine', editorials Can Fam Physician 35:703-704 and 743-745.
- 11 Sato A (1980) 'Physiological Studies of the Somatoautonomic Reflexes' Chapter 5 in 'Modern Developments in the Principles and Practice of Chiropractic', ed by Haldeman S Appleton, Century, Crofts, New York.
- 12 Leach RA (1986) 'Somatoautonomic Reflex Hypothesis' Chapter 11 in 'The Chiropractic Theories: A Synopsis of Scientific Research', Williams & Wilkins Baltimore (2nd edition).
- 13 Kunert W (1965) 'Functional Disorders of Internal Organs Due to Vertebral Lesions', CIBA Symposium $13(3) \cdot 85 \cdot 96$.
- 14 Korr IM (1977) 'The Neurobiologic Mechanisms in Manipulative Therapy' Plenum Press New York and London,
- 15 Rachlis M and Kushner C (1989) 'Second Opinion: What's Wrong with Canada's Health Care System and How to Fix It' Collins Toronto, 10, 48, 81.

Professional Notes: continued from page 1.

A recent international family medicine conference in Toronto focussed on "the respective roles of *quantitative* and *qualitative* research in ... family medicine and other forms of primary care". The consensus was "that qualitative studies are likely to have a central role in future research" even though it will be difficult to have them "accepted by the broader medical community."

Why did Dixon write this editorial? Because in that issue the Canadian Family Physician he publishes qualitative and anecdotal research papers from family medicine. He admits these would stand little chance of being published in research sections of prestigious medical journals", but is happy to publish because this technically poor science produces "a depth of understanding that might not be possible otherwise."

He compares primary practice – and it is the same in family medicine and chiropractic – with business, where there is also conventional research that extracts and isolates components of a problem. He quotes Russell Ackoff, one of the founders of business operations research, who says:

"Managers are not confronted with problems that are independent of each other, but with dynamic situations that consist of complex systems of changing problems that interact with each other. I call these situation *messes*.

Problems are abstractions extracted from messes ... managers do not solve problems: they manage messes."

Sound familiar? Good research may try to remove it, but the Hawthorne effect – the sympathetic ear of the trusted adviser at the right moment – is fundamental to your success with patients.

Erratum

The last issue of this Report (September 1989 Vol. 3 No. 6) made reference to the text 'Managing Low Back Pain' (1988) edited by Professor William Kirkaldy-Willis. This was published by Churchill Livingston, New York and London, not as incorrectly stated, by Williams and Wilkins, Baltimore and London.