

Nonionic contrast media: economic analysis and health policy development

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The replacement of old radiologic contrast media with supposedly safer but more expensive media has created a dilemma for radiologists and hospital administrators. To quantitate the nature of this trade-off we performed a cost-utility analysis using optimistic assumptions that favoured the new media. A complete conversion to the new media would result in an incremental cost of at least \$65 000 to gain 1 quality-adjusted life-year (QALY). For a selective strategy in which only high-risk patients would receive the new media the cost would be about \$23 000 per QALY gained. However, the incremental cost for low-risk patients is over \$220 000 per QALY gained. Conversion to the new contrast media, although not necessarily the most efficient use of scarce resources, has already occurred in Ontario, primarily because of press publicity, pressure from insurers and a political unwillingness of policymakers to decide the fate of identifiable victims. We found that funding of a new intervention associated with a high cost-utility ratio rather than interventions with lower ratios might save some identifiable victims at the expense of a larger number of unidentifiable ones.

Le remplacement des substances de contraste (SC) traditionnelles en radiologie par de nouvelles SC censément plus sécuritaires mais plus chères pose un dilemme au radiologue et à l'administrateur hospitalier. Nous avons quantifié ce débat par une analyse des coûts et des

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avantages fondée sur des suppositions tendant à favoriser les nouvelles SC. L'adoption exclusive de celles-ci coûterait au bas mot 65 000 \$ de plus pour gagner 1 "année de vie compte tenu de la qualité de celle-ci" (dite ici QALY). Un tel gain reviendrait à quelque 23 000 \$ en restreignant l'emploi des nouvelles SC aux malades à risque élevé mais dépasserait 220 000 \$ dans le cas des sujets à risque peu élevé. Le remplacement en question, sans la preuve qu'il constitue le meilleur emploi de ressources limitées, a déjà eu lieu en Ontario, à cause surtout des articles de presse, de l'influence des assureurs et du manque de volonté politique de la part des décideurs quant au sort des victimes susceptibles d'être reconnues. Nous trouvons que si, par le financement d'une nouvelle méthode à rapport coût-avantages élevé plutôt que de méthodes où ce rapport est plus bas, on cherche à épargner certaines des victimes susceptibles d'être reconnues, on fait un plus grand nombre de victimes qui ne le sont pas.

Contrast media traditionally used to enhance radiologic images have been associated with a low but calculable risk of major reactions, including death. The new contrast media, which are nonionic or monodimeric or have low osmolality, are purported to cause fewer complications, reduce patient discomfort and result in better images. The only readily perceivable drawback is that they are 3 to 15 times more expensive than the older media.¹⁻³

Hospitals, governments and third-party payers are faced with the dilemma of choosing between the old and new contrast media. The cost of conversion can consume a substantial part of the operating budget of a radiology department or, indeed, a hospital.

In Ontario pressure to adopt the new contrast media was initially resisted by the hospitals and the principal third-party payer, the provincial government. However, two relatively healthy people in their 30s died in 1985 during routine procedures involving old contrast media performed in small community hospitals. In each case the coroner's jury recommended that funds be provided by the

government for the use of the new contrast media, that informed consent be obtained from all patients before procedures involving contrast media and that patients be informed of the existence of alternative media.^{4,5} The government was not legally bound to follow these recommendations, but the cases received considerable press coverage, which increased the lobbying for conversion to the new media.

Because Ontario's universal, publicly funded health care system prohibits direct user charges to patients,⁶⁻⁸ hospitals have had only two options for funding this conversion: to reduce spending on other programs to stay within their global budgets or to apply to the government for additional funding. Office-based procedures have been funded through fee-for-service, but the technical component of the fee for most services would not even cover the cost of purchasing the new media.

To examine the economic impact of this new technology on health care in Ontario we performed a cost-utility analysis to determine the marginal cost-effectiveness of conversion to the new media. The viewpoint of the analysis was that of the health care system: costs to patients (in time and discomfort) or to society (in productivity losses) were not explicitly considered, although the threshold analysis allowed indirect consideration of these factors.

Cost-utility analysis compares the cost of an intervention with its benefits, measured in quality-adjusted life-years (QALYs).⁹ Marginal or incremental cost-utility ratios compare the incremental costs of a program with the incremental benefits and are helpful when these costs and benefits are greater than zero. Conversion to new contrast agents is a good example of such an intervention.

A comparison of the cost-utility ratios of all health care programs allows policy analysts to set up a priority list on the basis of efficiency criteria. This list, if used to allocate resources, would maximize the total expected improvements in health status achieved by a fixed amount of resources. However, as we shall demonstrate, efficiency considerations are not the only criteria used by policymakers for allocating scarce resources.

Methods

Structure

The problem was structured as a decision tree with two outcomes: costs and clinical effects (Fig. 1). Three choices were available at the decision node: to continue to use the old contrast media in all patients (old), to use preset criteria to select patients at high risk for administration of the new media (select) or to administer the new media to all patients (new). In each case the patient could either survive with no reactions or suffer a minor reaction (not leading to prolonged hospital stay or permanent disability), a major reaction (leading to

prolonged hospital stay and disability) or a fatal reaction.

Analysis

The marginal cost-utility ratio — the extra cost required to achieve one more QALY — was calculated for complete conversion to the new media. The ratios were expressed as cost per QALY gained. To calculate the ratios we estimated the expected values for the cost and utility of every branch of the decision tree (old, select and new) by multiplying the probability of each branch by the value assigned to the outcome of that branch and then adding these values. We then calculated the marginal costs and utilities by comparing the differences in costs and utilities between the pair of strategies being examined. The marginal cost was divided by the marginal utility to obtain the marginal cost-utility ratio. Table I shows sample calculations for the case in which the new media would reduce the risk of all reactions 10-fold.

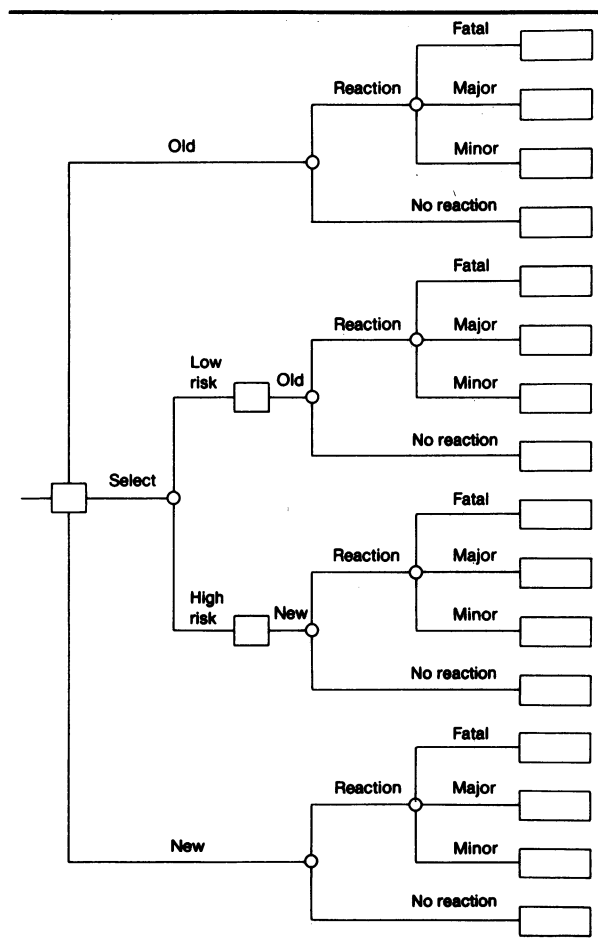


Fig. 1 — Decision tree for choosing to continue to use old contrast media in all patients (old), to administer new contrast media only to high-risk patients (select) or to administer new contrast media to all patients (new). Squares represent decision nodes, circles represent chance nodes, and rectangles represent terminal nodes.

Ratios were also calculated for a change from not giving the new contrast media to any patients (old) to giving it to all patients (new), from not giving it to any patients (old) to giving it to the 30% of patients at highest risk (select) and from giving it to the high-risk patients (select) to giving it to all patients (new).

There were no empirical values from established research for many of the estimates of probabilities, costs and utilities needed for the analysis; in these cases we estimated the values on the basis of whatever information was available. For the baseline analysis all of the estimates were biased in favour of the new contrast media; thus, the cost-utility ratios are probably lower than the true expected values. If the results were unfavourable, those obtained with the use of less biased estimates would be even more unfavourable.

Extensive sensitivity analyses were performed on all the variables; this included determining the effect that varying the values of the variables had on the results. All of the calculations were done with the use of the SmlTree software package (James Hollenberg, Pratt Medical Group, New England Medical Center, Boston, 1987).

Probabilities

Baseline probabilities for rates of complications with the old media were obtained from the largest and most often quoted studies of contrast media:¹⁰⁻¹² 1 in 20 procedures for minor reactions, 1 in 10 000 for major reactions and 1 in 40 000 for death. In the first analysis we assumed a 10-fold reduction in the relative risk for all types of reactions with the new media.¹³ This value, often quoted by proponents of the new media, is probably much greater than the true reduction of risk.

For screening purposes the relative risk of reactions in high-risk groups¹⁴⁻¹⁶ and the estimated proportion of patients in each risk category were used to construct a risk profile for a radiology department in a general hospital (Table II). Radiologists were asked to estimate the expected propor-

tions of patients in each category. Extensive sensitivity analyses were performed on the basis of these estimates, with little effect on the results. Marginal cost-utility ratios were then computed for changing the strategy from treating all patients with old media to treating high-risk patients with new media. Starting with a high-risk group that represented the 1% of the population at highest risk, we increased the size of this group in steps of 1%. With each increase the remaining patients at highest risk were included. The marginal cost-utility ratios were calculated for each step (Fig. 2).

For the screening strategy the relative risk of reaction in the low-risk group was adjusted to ensure that the overall risk in the total population remained constant. An optimal screening strategy was assumed: patients at highest relative risk of reactions would receive the new contrast media first. Any less efficient strategy would, of course, decrease the cost-effectiveness of this approach.

Cost estimation

The average cost per dose of contrast media, estimated on the basis of prices quoted by suppliers for bulk purchases, was \$9 for the old media

Table II — Distribution of high-risk patients in a radiology department of a general hospital by category of risk

Category of risk	Relative risk*	% of patients
Previous reaction to contrast media	10.0	1
History of heart disease	8.5	5
Undergoing angiography	8.0	5
Asthma	5.1	1
History of allergy	3.0	1
Age > 60 yr	3.0	20
History of drug reactions	3.0	1
Renal insufficiency	1.8	1
Diabetes mellitus	1.1	5

*Relative risk of reaction to old contrast media.¹⁴⁻¹⁶

Table I — Sample calculation of cost-utility ratios associated with a 10-fold reduction in relative risk with the use of new contrast media

Treatment program	Cost, \$	Utility, QALY*
Old†	14.3872	29.9986
Select‡	36.9842	29.9996
New§	97.5388	29.9999

Program change	Marginal cost, \$	Marginal utility, QALY	Marginal cost-utility ratio, \$/QALY
Old to new	83.1516	0.0013	63 963
Old to select	22.5970	0.0010	22 597
Select to new	60.5546	0.0003	201 849

*QALY = quality-adjusted life-year; based on a life expectancy of 30 years.

†Use of old contrast media in all patients.

‡Use of new contrast media in only high-risk patients.

§Use of new contrast media in all patients.

and \$97 for the new. We calculated the averages by weighting the volume of media required for various procedures by the distribution of these procedures in a radiology department. If a 20-fold difference in cost, which has been reported in the United States,¹⁷ were used in the analysis the resulting cost-utility ratios would be more unfavourable.

Because there was little empirical information on the cost of reactions, we attempted to favour the new contrast media as much as possible and estimated the costs as follows: minor reaction \$100 (a very high estimate because most minor reactions resolve with no treatment or with the use of inexpensive therapy) and major reaction \$3877 (on the basis of 3 days in an intensive care unit at \$919/d and 1 week on a ward at \$160/d). The daily costs of care were obtained from the records of the Toronto General Hospital and included full overhead allocation.¹⁸ Because major reactions are not always handled in teaching hospitals, do not always require intensive care and at most usually add only a few days to the patient's hospital stay our bias continued to favour the new media.

Although fatal reactions often occur immediately, many of the patients die after several days in hospital; therefore, we assumed that the costs incurred before death would be similar to those of a major reaction. Although death clearly imposes high costs on the patient's family and on society these costs are indirectly considered in the price one will pay to gain an additional QALY.

The costs in our analysis were estimated from the perspective of the medical care system and were expressed in 1986 Canadian dollars.

Utility estimation

For the baseline case we used an average life expectancy of 30 years after the administration of contrast media. Using a utility scale of 0 for death and 1 for perfect health we arbitrarily assigned a value of 0.7 to all the remaining life-years for patients suffering major reactions, which is similar to the values given to life with severe disabilities.¹⁹ This supports the bias against the old media, because most reactions do not result in such severe consequences. There was no change in the utility assigned to the health status after a minor reaction, because the results have no discernible effect on lifetime utility.

Results

Given the most optimistic assumptions of the baseline case, the marginal cost-utility ratio was approximately \$65 000 per QALY gained for complete conversion to the new media. If our estimates of the variables were indeed biased in favour of the new media, then the true ratio would probably be even higher. The sensitivity analysis revealed how this ratio changed as the estimated reduction

of relative risk varied (Fig. 3): as the benefit from conversion to the new media decreased, the ratio became quite large. When the estimated relative risk was reduced threefold¹⁵ the marginal cost-utility ratio was \$89 000 per QALY gained. Indeed, these estimates of risk reduction are based on studies involving small samples and have 95% confidence limits that overlap a relative risk reduction of 1. Thus, the true values of these cost-utility ratios could be far greater if the risk reduction were closer to or less than 1.

The marginal costs were relatively stable until the size of the high-risk group reached about 30% of the population. This size of group was then used to represent patients at high risk and included those with a history of reactions to contrast media, heart disease, allergy and asthma, those undergoing angiography and those over the age of 60 years. Even with the use of different profiles the cutoff point remained within 25% to 40%.

The marginal cost-utility ratio for administering new contrast media to the 30% of the popula-

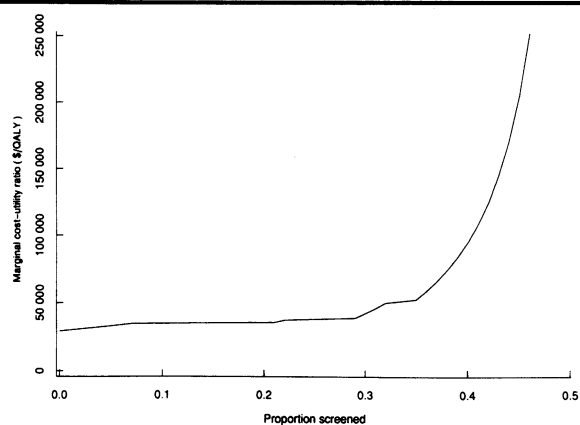


Fig. 2 — Marginal cost-utility ratios (cost per quality-adjusted life-year [QALY] gained) by size of high-risk group. Values represent marginal ratios for treating additional 1% of population.

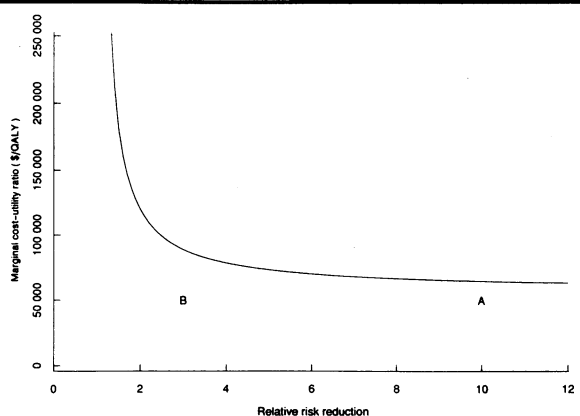


Fig. 3 — Marginal cost-utility ratios for complete conversion to new contrast media as function of reduction in risk attributable to new contrast media. Tenfold reduction in relative risk (A) was used in baseline case; threefold reduction in risk (B) may be more reasonable.

tion at highest risk was \$23 000 per QALY gained, assuming a 10-fold reduction in risk, perfect assignment to risk status and administration of new media to the people at highest risk first. The ratio

for the remaining 70% of the population was \$220 000 per QALY gained. If the reduction in relative risk is threefold these values become \$57 000 and \$315 000 respectively.

Comparisons with the cost-utility ratios of other health care programs are shown in Table III. Because all of the estimated variables were biased in favour of the new contrast media the cost-utility ratios calculated for conversion should be less than the true values.

The results of the threshold analyses are shown in Table IV. The thresholds are the values each variable would have to reach so that the marginal cost-utility ratio for complete conversion would fall below a preset value, all other variables remaining constant. We selected a threshold of \$20 000 per QALY gained, because many of the programs routinely funded in Ontario (e.g., screening programs for hypertension) fall at or below this level. Under the optimistic assumption of a 10-fold reduction in risk for the new media the results of the threshold analysis showed that the cost of the media would have to decrease from \$97 to \$39.50 per dose before the ratio would reach \$20 000 per QALY gained. If the reduction were threefold the price would have to decrease to \$22.

Table III — Cost-utility ratios of health care programs^{19,20}

Program	Cost-utility ratio, \$/QALY gained*
Screening for phenylketonuria	< 0
Postpartum anti-D therapy	< 0
Antepartum anti-D therapy	1 480
Coronary artery bypass surgery for left main coronary artery disease	5 100
Neonatal intensive care for infants weighing 1000 to 1499 g	5 460
Screening for thyroxine deficiency	7 650
Treatment of severe hypertension (diastolic pressure \geq 105 mm Hg) in men aged 40 yr	11 400
Administration of new contrast media to 30% of population at highest risk, with 10-fold reduction in relative risk	23 000
Treatment of mild hypertension (diastolic pressure 95 to 104 mm Hg) in men aged 40 yr	23 175
Estrogen therapy among postmenopausal women who have not had hysterectomy	32 760
Neonatal intensive care for infants weighing 500 to 999 g	38 580
Coronary artery bypass surgery for single-vessel disease in patients with moderate angina	44 400
Tuberculin testing in school	53 000
Continuous ambulatory peritoneal dialysis	57 100
Complete conversion to new contrast media, with 10-fold reduction in relative risk	64 000
Hemodialysis in hospital	65 500
Administration of new contrast media to low-risk patients, with 10-fold reduction in relative risk	220 000

*Values adjusted to 1986 US dollars.²¹

Discussion

Given the current evidence the marginal costs required to achieve the health benefits associated with complete conversion to the new contrast media exceeded those associated with most health programs, even when our estimates favoured the new media. The ratio for selective use of the new media among only high-risk patients may be comparable to that for other programs such as hypertension screening (Table III). Provision of the new media to low-risk patients appears to be far less cost-effective. However, a certain degree of inefficiency may be acceptable to achieve other objectives, such as fairness and equity. For example, many social programs or government subsidies are used to redistribute resources to some groups

Table IV — Values required to achieve a cost-utility ratio of \$20 000 per QALY gained

Variable	Baseline case	Threshold analysis	
		Tenfold reduction in risk	Threefold reduction in risk
Cost, \$			
Death	919	2 380 000	4 505 000
Major reaction	3 877	597 000	1 129 000
Minor reaction	100	1 390	2 271
Nonionic contrast media	97	39.50	22
Probability of reaction to old media			
Death, per 100 000 population	2.5	13.0	23.0
Major reaction, per 1000 population	1.0	44.0	34.3
Minor reaction, per 100 population	5.0	6.8	> 99.0
Quality adjustment for life after major reaction	0.7	< 0	< 0
Life expectancy, yr	30	97	> 100

who are deemed to be deserving, even though the overall efficiency is reduced. Considerations such as these, along with political pressures, almost always dominate the priority-setting process.

The Ontario Council of Administrators of Teaching Hospitals held a consensus conference in Toronto on Nov. 13, 1986, to make recommendations on the selection of appropriate contrast media. The participants included radiologists from the province's five health sciences teaching centres, representatives of each radiologic subspecialty and observers from the Ontario Hospital Association, the Ontario Medical Association and the Ontario Ministry of Health. The results of our cost-utility analysis had been made available to the organizers before the conference but were not presented formally.

At the conference the concept of development of a screening strategy was dismissed as being unfeasible. The physicians would not accept the risk of even one adverse reaction to the old contrast media; therefore, they were unwilling to deny the new media to anyone.

The radiologists were greatly influenced by pressure from the patients, the press and the liability insurers¹³ and felt they had little choice but to push for complete conversion — to the dismay of other health professionals (*Globe and Mail*, Toronto, Aug. 19, 1986: A7).

The insurers indicated that because of the possibility of malpractice litigation they would not insure radiologists who used the old media. The insurers did not have to bear the costs of conversion, yet stood to gain because they might face fewer instances of liability.

Radiologists in private practice in Ontario, unable to have the technical components of the fee schedule increased to cover the costs of the new media, stopped doing many or all of the procedures that involve contrast media, thereby increasing the burden on hospital radiology departments. The hospitals, unwilling or unable to cut other programs and prohibited from charging patients, appealed to the Ontario government, which finally provided additional funds.

Other options, such as the development of a screening strategy and the provision of liability coverage for hospitals and radiologists to counter the insurers, would have been less expensive than complete conversion but not as politically expedient. Another option, the encouragement of pretreatment with steroids among high-risk patients, which has been shown to reduce the risk of reaction to contrast media,²² would not resolve the problem, because patients would be selected to receive the old media, pretreatment or the new media.

In November 1986 the Ontario government announced a special allocation program to cover the extra costs of the new media. Obviously the funds could be obtained only by reducing or eliminating other programs. Because few health care programs have been evaluated for their effec-

tiveness, let alone their cost-effectiveness, the allocation program's effect on the efficient use of resources is unknown. However, complete conversion to the new contrast media, particularly among low-risk patients, does not appear to be as efficient as selective conversion. Given the climate of cost constraints and cutbacks in services in Ontario, the money allocated for complete conversion might have been better spent.

Our analysis is a clear example of what Calabresi and Bobbitt called the "identifiable victim".²³ It is easier to deny funding to programs if there are no identifiable victims. The political and legal forces that pressed for the adoption of the new contrast media refused to make a decision that could be interpreted publicly as placing a finite value on a life. In this sense the role of the coroner's inquests in identifying the lost lives was fundamental. If funds were denied for the new contrast media every adverse reaction to the old media would result in a finding of negligence. Conversely, if funds were denied for health promotion programs that save statistical lives, such as antismoking programs and those that enforce drinking and driving laws, it would be difficult to identify the people denied the potential benefits, especially if the benefits accrue in the distant future.

Such economic studies as cost-utility analysis explicitly demonstrate the resource implications of allocation decisions. Policymakers and society often have difficulty in accepting this information. In addition, political pressures may lead to inefficient choices that seem to provide satisfactory results. Nevertheless, society must be aware that an extra price has been paid to attain these outcomes. If funds are transferred from programs with lower cost-utility ratios to programs with higher ratios some identifiable victims might be saved, but many more unidentifiable ones might be lost.

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Incidence of infantile hypertrophic pyloric stenosis in Saskatchewan, 1970-85

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We reviewed the incidence rates of infantile hypertrophic pyloric stenosis (IHPS) and pylorospasm in Saskatchewan from 1970 to 1985 and found a marked decrease in the rates after 1976. As expected, there was a preponderance of males among those with IHPS and among those with pylorospasm discharged from hospital between 1 and 3 months of age. No seasonal pattern was observed. We believe that the decrease in incidence rates was related to environmental influences, such as changes in the methods of feeding observed since 1977.

L'examen de la fréquence de survenue de la sténose hypertrophique du pylore (SHP) et du pylorospasme chez les nourrissons en Saskat-

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chewan, de 1970 à 1985, montre que cette fréquence a baissé significativement après 1976. On trouve la prédominance attendue de garçons parmi ceux qui ont présenté une SHP et ceux qui, ayant manifesté un pylorospasme, ont quitté l'hôpital entre les âges de 1 et de 3 mois. Il n'existe aucune fluctuation saisonnière. La chute de fréquence s'explique selon nous par des facteurs extrinsèques, notamment les changements survenus dans le mode d'allaitement depuis 1977.

The incidence rate of infantile hypertrophic pyloric stenosis (IHPS) has varied around the world at different times¹ but has usually been between 1 and 3 per 1000 live births in the Western world.¹⁻⁷ From 1980 to 1984 several investigators⁸⁻¹¹ in Britain suggested that the incidence rate had increased since the early 1970s.

Reports from the United States have indicated that the incidence rate of IHPS is higher among white infants than among black infants,² and one study from Hawaii showed a very low rate among