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Regulating the private health care sector: the case of the Indian Consumer Protection Act

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Private medical provision is an important constituent of health care delivery services in India. The quality of care provided by this sector is a critical issue. Professional organizations such as the Medical Council of India and local medical associations have remained ineffective in influencing the behaviour of private providers. The recent decision to bring private medical practice under the Consumer Protection Act (COPRA) 1986 is considered an important step towards regulating the private medical sector. This study surveyed the views of private providers on this legislation. They believe the COPRA will be effective in minimizing malpractice and negligent behaviour, but it does have adverse consequences such as an increase in fees charged by doctors, an increase in the prescription of medicines and diagnostics, an adverse impact on emergency care, etc. The medical associations have also argued that the introduction of COPRA is a step towards expensive, daunting and needless litigation. A number of other concerns have been raised by consumer forums which focus on the lack of standards for private practice, the uncertainty and risks of medicines, the effectiveness of the judiciary system, and the responsibility of proving negligence.

How relevant are these concerns? Is the enactment of COPRA really appropriate to the medical sector? The paper argues that while this development is a welcome step, we need to comprehensively look into the various quality concerns. The effective implementation of COPRA presumes certain conditions, the most important being the availability of standards. Besides this, greater involvement of professional organizations is needed to ensure appropriate quality in private practice, since health and medical cases are very different from other goods and services.

The paper discusses the results of a mailed survey and interview responses of 130 providers from the city of Ahmedabad, India. The questionnaire study was designed to assess the opinion of providers on various implications of the COPRA. We also analyze the data on cases filed with the Consumer Disputes and Redressal Commission in Gujarat since 1991. Four selected cases filed with the National Commission on Consumers Redressal are discussed in detail to illustrate various issues affecting the implementation of this Act.

Introduction

Private provision of health care is an important constituent of the health care delivery system in India and its role has increased considerably over time (Bhat 1993). At present about 70% of hospitals and 50% of hospital beds are in the private for-profit and non-profit sector. This sector employs about 70% of qualified doctors (Jesani and Anantharam 1989). Most of the newly qualified doctors prefer either to start their own private practice or to work in private hospitals. Utilization studies show that health care services provided by this sector are used not just by the affluent classes; a large number of poor people use them and have exhibited their preferences in approaching private doctors for their health problems (Duggal and Amin 1989). The share of the private health care sector in GDP is estimated to be about 5% (Satia et al. 1987).

The growth of the private sector raises a number of concerns (Bhat 1993), most of which stem from reasons of market failure. The State is supposed to play an important role in regulating this sector but it has so far remained passive. State interventions have been minimal, leaving this sector to grow *laissez-faire*. The role of medical associations and medical councils has been equally minimal. Undesirable practices have grown considerably, thus

affecting the quality of care. The growing dissatisfaction with the services offered by this sector, and increases in medical negligence cases, have attracted the attention of the consumer movement in the country. Private medical practice has now been brought under the Consumer Protection Act (COPRA), 1986.

This paper discusses the issue of bringing private medical practice in India under the COPRA. It addresses the following questions arising from recent experience:

- Is a private medical service a type of commercial service? Can a consumer of medical services seek redressal in consumer courts for malpractice and negligent treatment?
- How have medical associations and medical councils viewed the inclusion of private medical practice under the jurisdiction of COPRA?
- What are the concerns and issues raised in cases filed with the consumer forums?
- Do private providers think COPRA will be effective in its objective? What are the implications of bringing private medical practice under COPRA?

The application of COPRA to private medical practice is considered an important step in ensuring that patients receive an appropriate quality of care. The medical associations have not welcomed this development. The medical councils have refrained from making any comment on this Act. The findings of the current study reveal that private providers believe COPRA will be effective in minimizing malpractice and negligent behaviour. However, the legislation does have a number of adverse consequences, including: increases in fees charged by doctors, increases in the prescription of medicines and diagnostics, adverse impacts on emergency care. A number of other concerns have been raised in consumer forums during the hearing of complaints. These concerns relate to the lack of standards for private practice, difficulty in differentiating between mistaken diagnosis and negligent behaviour, risks and uncertainty in the medical sector, the effectiveness of the judiciary system, and responsibility to prove negligence.

While this development is a welcome step, the paper argues that a broad strategy is needed to look at various concerns afflicting the private health care sector. Health and medical care services are very different from other goods and services. The effective implementation of the Act presumes certain conditions, the most important being the availability of standards. We suggest that though the COPRA is highly desirable, health and medical cases should be dealt with differently from other services. We also suggest that the quality of private health care should be viewed in a broader context and attempts should be made to address all the issues. Professional organizations such as medical councils and medical associations should have an important role in this area.

The paper discusses these questions using cross-sectional data collected from a survey and interviews of doctors in Ahmedabad. The study also uses information relating to cases filed with the National Commission and State Commission in Gujarat. Part I of the paper explains the broad purpose of the Consumer Protection Act, 1986, and its applicability to private medical practice. Part II delineates the issues raised in consumer forums. For this purpose we have selected four cases heard by the National Consumer Disputes Redressal Commission, New Delhi, from 1989 to 1993. Part III discusses the findings of the survey and interviews of doctors in Ahmedabad city. The final part summarizes the policy implications of this paper.

Part I: The Consumer Protection Act, 1986

It is well established that leaving health care to market forces does not lead to an effective and efficient health care system (Bennett et al. 1994). This is because a complex set of market distortions and market imperfections interact with moral hazard problems of market and information asymmetry, leading the market to be inadequate and to have high costs. It is argued therefore, that the state has an important role in ensuring the safe and appropriate delivery of health care services from this sector. However, not many initiatives have been taken by the state to regulate the sector's services, though the sector has grown significantly. As far as the introduction of legislation is concerned, there are only a few examples of regulations promulgated by the state at local government levels, e.g. the Nursing Home Acts of Delhi and Bombay. The implementation of these regulations has always been a problem (Nandraj 1994), and most of the provisions of these legislations are now outdated anyway. Since health is a state subject in India, a large number of local governments have not implemented similar types of legislation. Other regulations and standards (e.g. the Drugs and

Cosmetics Act, Pharmacy Act, Bureau of Indian Standards, etc.), which have implications for quality of health care, have been ineffective in regulating this sector.

The professional bodies governing the medical profession, such as the Medical Council of India, are another source of influence on the behaviour of private providers. These professional bodies prescribe the code of conduct which each practising member is supposed to observe and ensure that he behaves according to the expectations of these bodies. Generally, it is expected that the medical profession will work through self- and peer-regulation. However, over time the medical associations and councils etc., which were expected to play this role, have lost their influence in regulating the behaviour of private providers. Also, a large number of physicians are not active members of these associations and those who are are often not very concerned about association guidelines.

As a result, with the growth of this sector the prevalence of certain practices, such as fee-splitting, over-prescription of medicines and drugs, inadequate sterilization procedures, and employing untrained personnel, has increased. These undesirable practices are known to adversely affect the quality of health care. Apart from unnecessary and ineffective care (as a result of demand inducement), the negligent practices cause immediate harm to the patient, because of not following minimum standards or lack of desirable skills. This has attracted the attention of consumer movements in India. Recent legislative reforms in India have brought medical services provided by the private for-profit sector under the Consumer Protection Act (COPRA), 1986.

The COPRA was promulgated to protect the interests of consumers through the establishment of consumer councils. The objectives of this Act are: 1) to promote and protect the rights of consumers; 2) to provide a right to information and to protect the consumer against unfair trade practices; 3) to ensure that consumers' interests will receive due consideration at appropriate forums. These objectives are promoted by the consumer protection councils established at the district, state and national level. Speedy and simple redressal is provided by quasi-judicial bodies, again at district, state and national levels. According to this Act, a consumer of services is a person who 'hires or avails' services for a payment. This also includes the beneficiary of such services other than the person who actually hires the services. Services of any description made available to potential users are included in the Act.

The purpose of the COPRA is to provide less costly and speedy remedy to aggrieved consumers than the alternative, time-consuming and expensive process of civil litigation. The Act specifically invests the redressal forums with the powers vested in the civil court for the summoning of witnesses and their examination under oath, the production of documents and other materials as evidence, etc. (COPRA 1986).

Redressal mechanisms

Under this Act a complaint can be filed by an individual consumer, a registered consumer association or the central or state government and a group of consumers with the same interests. A complaint can be lodged if the consumer of services suffers from a deficiency that could be a fault, imperfection, shortcoming or inadequacy in the quality, nature, or manner of performance that is required in relation to a service. The state governments have established district forums and state level commission to handle the redressals. The central government has also established a national level commission to address the consumer disputes redressal.

The 'district forum' consists of a president (qualified district judge) and two members who are appointed by the state government. The district forum considers complaints where the value of goods and services and the compensation does not exceed Rs. 5 lakhs (about US$17 000). Appeals against orders of the district forum can be made to the State Commission within a period of 30 days. Like district forum, the State Commission also consists of a president and two other members. The State Commission has the jurisdiction to consider complaints where the compensation is between Rs. 5–20 lakhs (about US$17 000–70 000) and appeals against the order of the district forum. Similar to district forum, appeals against State Commission orders can be made to the National Commission. The National Commission consists of a president, who is or has been a judge of the Supreme Court and is appointed by the central government, plus four other members. The National Commission has the jurisdiction to consider complaints where the value of goods, services or compensation exceeds Rs. 20 lakhs (about US$70 000) and appeals against the order of the State Commission. The orders of the National Commission can be appealed against in the Supreme Court.

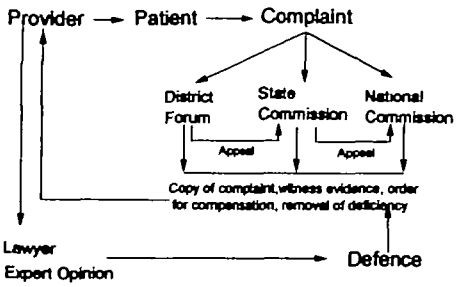

Figure 1. Redressal mechanism for handling complaints

The district forum, State Commission and the National Commission will not admit a complaint unless it is filed within one year from the date on which the cause of action has arisen. Every order passed by any of these three councils will be enforced in the same manner as if it were an order made by a court. If the person against whom the complaint is made fails to comply with the order, then he/she is punishable with imprisonment for a minimum of one month and maximum of three years and/or with a fine between Rs. 2000-10 000 (about US$75-300). The procedure of handling the complaints is explained in Figure 1.

Upon receiving a complaint, the district forum refers a copy of the complaint to the opposite party directing them to give their version of the case. If the opposite party denies or disputes the allegations, the district forum proceeds to settle the dispute. The district forum can summon, enforce attendance of the defendant and witness, and examine the witness under oath. Every proceeding before the district forum will be a judicial proceeding to be tried under the Indian Penal Code (sections 193 and 228) and the district forum will have the powers of the civil court (section 195 and chapter XXVI of the Code of Criminal Procedure, 1973). If the district forum is satisfied with the allegations contained in the complaint, it will 1) issue an order to the opposite party directing them to pay such amount as may be awarded by it as compensation to the consumer for any loss or injury suffered due to the negligence of the opposite party, 2) remove the deficiencies in the services in question, and 3) provide for adequate costs to the parties. Every proceeding requires the presence of the president of the district forum and at least one member of the forum.

A number of concerns have been raised about the application of this Act to private medical practice. *Inter alia* these include whether medical services fall under the broad definition of the Act, and whether the legal heirs of the deceased are consumers. These issues are discussed below.

Is medical service a type of personal service?

The COPRA does not include medical services in its list of specified services. The word 'service' can be interpreted to include every conceivable kind of service in which any benefit, use or advantage is derived for a payment. However, two categories of service are exempted from the purview of this Act. These are services rendered free of charge or under the contract of personal service. However, the nature of personal services has not been explained or clarified in the Act.

The implication of these two exemptions is that medical services in the public sector are excluded from the Act. Private providers have argued that a service rendered by a medical practitioner is a type of 'personal service' and is not the same as a service relating to a 'commercial transaction' that is included in the Act. Private providers, therefore, argue that the services provided by them should not be included.

In two cases, *M/s. Cosmopolitan Hospitals and another (appellants) vs. Vasantha P Nair (respondents)* and *Vinitha Ashok (complainant) vs. Lakshmi Hospital and Others (opposite parties)*, filed with the State Commission, the defendants (private doctors) claimed that these cases could not be tried under the COPRA. They argued that the services rendered to the patients were in the nature of personal services not commercial transactions and, hence, did not fall under the purview of the Act. They also argued that the aggrieved party cannot be considered 'consumers' of the services and, therefore, cannot file a complaint of medical negligence. The State Commission rejected the claim of the defendants and they appealed to the National Commission. The National Commission ruled that the judgement of the State Commission was appropriate. The Commission gave the following reason:

> 'According to the act, service is defined broadly and applies to every situation where there is a **'contract for service'** in which the renderer of service is independent of any supervision or control of the person who demands service. In the case of medical service, the patient is not in a position to exercise any control over the work of the doctor. This is a case of a principal-agent relationship, where the principal (i.e. the patient) authorises the doctor (i.e. the agent) to act on his

behalf so that in essence, the principal is hiring professional help for something of which he has no knowledge. Personal service, on the other hand, involves the **'contract of services'** which implies a master–servant relationship whereby the master directs the servant to perform services of a certain kind in a certain manner (i.e. master supervises the renderer of services). Therefore, professional services and technical services, such as those of surgeons, lawyers, accountants, engineering contractors, etc., are covered under COPRA.'

The court also passed the judgement that the complainants are legal representatives of the deceased and hence are vested with the inheritable rights of the deceased. They are vested with the power of enforcing the cause of action and can be considered 'consumers' under the Act.

In summary, recent legislative judgements have now made it possible to bring private medical practice under the purview of COPRA. The term 'personal service', exempted by the Act, has been interpreted as a service provided by a private individual to a particular person or relating to persons, and such service has been performed with the intervention of the latter. Medical services definitely do not fall into this category.

Response of medical associations to these developments

The Indian Medical Association has challenged the judgement in the Supreme Court on the grounds that it cannot include personal contracts within its purview.[1] All personal contracts are exempted from the Act. They argue that the Act reduces the medical services to a seller–buyer relationship. In the *M/s. Cosmopolitan Hospitals and another vs. Vasantha P Nair* case the Indian Medical Association and the Qualified Private Medical Practitioners Association, Kerala, appealed to intervene on behalf of the defendants. They argued that the issues raised were of grave concern and interest to members of the association and the medical profession at large. The two associations pleaded that this case should be tried under the Indian Medical Council Act, 1956, because this Act covers medical doctors and supersedes the Consumer Protection Act, 1986. They argued that the COPRA cannot have any application to the members of the medical profession.

The National Commission did not find merit in this plea. The Commission argued that the Indian Medical Council (IMC) Act provides for membership guidelines to the medical council, recognition of medical qualifications awarded by universities or medical institutions in India, and the maintenance of a medical register in every state in which it is required that every person wanting to practise medicine has to register with the council. Furthermore, the IMC Act provides for the prescription of minimum standards of medical education, for granting degrees, for professional standards, and a code of ethics for medical practitioners. The IMC Act empowers the council to remove any person from the register on grounds of professional misconduct. However, this Act does not contain provisions to protect the interests of persons who may suffer because of any negligence or deficiency in services rendered by members of the medical profession, i.e. the rights of a patient. It was ruled that since the IMC Act does not provide for the rights of the patient, this case should be tried under the Consumer Protection Act.

Another argument made by medical associations and doctors opposing the COPRA emanates from fears of the misuse of the Act against private providers. However, this argument seems to be unfounded. We looked at cases filed with the Consumer Disputes and Redressal Commission (CDRC), Gujurat. Figure 2 presents data on the number of filed and disposed of cases with the CDRC, Gujarat, since 1991. Of the total number of cases disposed of, 71% went in favour of doctors.

In summary, legislative rulings have ratified that private medical services are in the nature of **'contract for services'** where the relationship between the patient and doctor is of principal and agent. The doctor takes all decisions on behalf of the patient and therefore such services are within the purview of the COPRA. It has also been established that the relatives of the deceased are legal representatives with all the rights of the deceased and are vested with the power of enforcing the cause of action. However, the medical councils and medical associations have not yet accepted COPRA's applicability to private medical practice in principle, though the argument that COPRA will always be unfavourable to doctors is unfounded.

Part II: Issues raised in consumer forums

Many other concerns have been raised in consumer forums by providers and consumers. This section examines the four cases of medical negligence filed

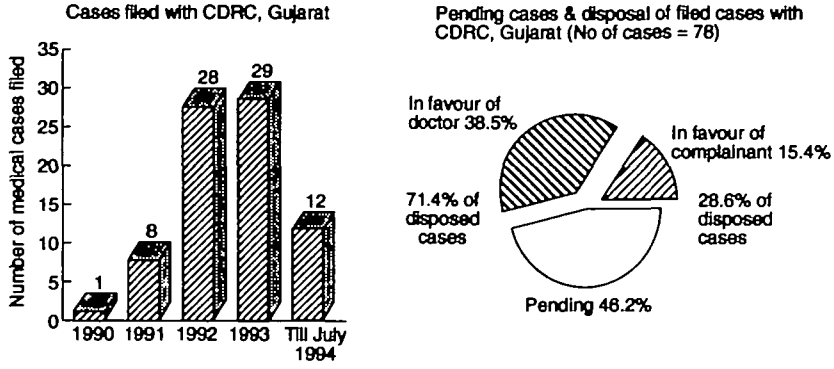

Figure 2. Medical cases filed with the Consumer Disputes Redressal Commission (CDRC), Gujarat, 1990–1994

with the National Commission from 1989–1993.[2] The main issues are as follows:

- How important are uncertainties and imperfections in medicine?
- Whose responsibility is it to prove medical negligence?
- Is the judiciary system effective?

The outcome and main issues arising out of the analysis of these cases are discussed below.

Uncertainties and imperfections in medicine

Are doctors expected to use the highest level of skill? Is it possible to make a distinction between mistaken diagnosis, negligent behaviour and cause of death? How important are uncertainties and imperfections in medical interventions and procedures? These are some of the concerns raised in various cases filed with the consumer forums. According to the complainant in the case *Vinitha Ashok vs. Lakshmi Hospital and Others* an unnecessary operation was performed resulting in the removal of a vital organ. The complaint filed was that the operation was conducted without proper examination and diagnosis, and therefore the doctor should be held liable for negligence.

The consumer forum examined the case with the help of an expert (professor and head of the department of obstetrics and gynaecology) and ruled that it is not necessary to establish that the doctor should use the highest degree of skill. It is enough for the doctor to show that he/she has acted according to the general and approved practice. *A mistaken diagnosis is not necessarily a negligent diagnosis*. A practitioner can only be held liable if his/her mistake is of a nature to suggest absence of reasonable skill as compared to the ordinary (expected) level of skill.

In another case, *Renu Jain and Others vs. Escorts Heart Institute and Research Centre*, the consumer forum was confronted with the question of determining the cause of death where a complicated procedure was performed. The consumer forum observed that generally there is a problem in establishing medical negligence because the lines between error of judgement, unforeseen complications and negligence are blurred.

The above cases highlight the point that, in medical practice, even if the doctor has acted according to general and approved practice, his action may still cause loss to the patient. This may happen because of the imperfections in medical science or may be due to diagnostic procedures. The doctor should not be held responsible for any loss arising out of these imperfections. These cases have recognized two points. First, almost all medical interventions and procedures have inherent risks, and secondly, doctors face a considerable amount of uncertainty. The nature of a patient's problem and its outcome contribute to the uncertainty. In the medical profession, for any procedure (including accepted diagnostic techniques) and intervention there is always some small probability of adverse consequences. This means that while a large number of patients derive advantage from a procedure, a small percentage may be affected adversely. It may not be possible for the physician to eliminate this possibility completely and to predict the potential sufferer and the loss it may cause. It is also possible that the doctor will use a procedure to minimize the ill-effects of some larger risk and in the process may cause some injury or harm to the patient.

Furthermore, where the treatment of a patient is a race against time (e.g. in the case of an operation, the consumer forums have made allowance in favour

of the provider by applying a risk-benefit test. If the doctor follows a course of treatment or procedures accepted and followed by a responsible section of the profession, he/she is not guilty of negligence even if another section of the profession does not subscribe to that practice. The National Commission has recognized this fact. It has ruled that if a doctor has acted according to general and approved practice, he cannot be charged under the COPRA for the inherent imperfections and risks in medical practice.

One may also observe from these cases that the consumer forums are not equipped with the necessary expertise to handle medical negligence cases and, therefore, the practice of co-opting a physician member in the forum has been developed to handle such cases.

Whose responsibility is it to prove medical negligence?

In cases of medical negligence, the onus of proving that the mistake was a result of negligence is on the complainant. In the cases of *Vinitha Ashok vs. Lakshmi Hospital and Others* and *Renu Jain and Others vs. Escorts Heart Institute and Research Centre* complainants faced problems in getting qualified medical practitioners to testify on their behalf, whereas the defendants did not. Getting doctors to testify and explain the finer points of medical jargon may be difficult in cases of medical negligence. The complainants in the above cases were unable to furnish adequately qualified witnesses on their behalf.

Thus, one problem for patients when trying to prove negligence is access to experts with their specialist knowledge, and hence, access to specialist information. Doctors are usually in a more advantageous position, having more information on the case. Under the present scenario, in most cases private providers do not make the diagnosis information available to their patients. In many situations where the providers are dispensing their own medicines, patients have no knowledge of the medicines they consume. Under these circumstances, a patient is not in a position to put together all the necessary information and documents as evidence, and may have to incur higher transaction costs if he/she decides to file a negligence case in the consumer court. The effect of all this is that the patient suffers economically as well as physically.

Present medical practice is primarily governed by the code of conduct laid down by the medical council. The responsibility for implementing the code lies with the medical associations and councils, but we have found no evidence of these institutions assuming any such responsibility for implementing the code or other regulations. Doubts have been raised about the capacity of these institutions to implement such guidelines; they do not have the necessary infrastructure and lack effective mechanisms to handle these issues. No attempt has been made by these institutions to develop an inventory of standard norms for general and approved practice. Without such standards, the rulings and judgement in consumer forums will likely be affected by whoever makes a more forceful argument and amasses more evidence. Judgement of non-technical persons is influenced by expert opinion; thus the procedure is prone to considerable subjectivity. Certainly, the COPRA does not ensure implementation of a code of conduct or code of ethics. Whoever can mobilize expert opinion in his/her favour will have the advantage.

These cases illustrate that filing a complaint of medical negligence may prove to be a costly business for a patient. It certainly requires financial and other resources to put together the minimum amount of evidence and witnesses. This also requires some knowledge of medicine. Though the Act offers a relatively quick and low-cost way of redressal, it is likely that the proportion of cases filed by the lower socioeconomic classes will be minuscule; in most cases they will probably decide not to file the complaint.

Is the judiciary system effective?

There are cases where the complainants have experienced considerable difficulty in interpreting the law and the position taken by various councils. The complainant in the case of *S.K. Abdul Sukur vs. State of Orissa* alleged that there was negligence in the cross-matching of blood and that hospital authorities were also negligent in completing certain formalities considered necessary in the case. The State Commission disposed of the complainant by arguing that oral evidence and cross-examination were necessary for the purpose, and hence the competent forum in this case would be the civil court. The National Commission reviewed this case and ruled that the State Commission was not justified in referring the matter to the civil court. The National Commission observed the following:

> '. . . The COPRA clearly indicates that the redressal forums are to decide the cases filed

> before them after taking such oral and documentary evidence into account. Decline of jurisdiction by the special redressal forum on the mere ground that examination and cross-examination of witnesses would be necessary would amount to unjust denial of the benefits of the Act to the aggrieved consumer by erroneous abdication of its duties.'

The functioning of consumer forums is another area that is considered a major obstacle in implementing COPRA. At present there are about 500 consumer courts in the country. These are not adequately staffed and face considerable difficulty due to the lack of infrastructure. The number of cases filed with consumer forums is growing rapidly and they are unable to settle the cases within the stipulated time. As a result, the number of pending cases is also increasing; in total about 200 000 cases are currently pending with these forums. In the medical sector about 50% of the medical cases filed with the CDRC, Gujarat, were pending as of 30 June 1995. Part of the problem may be related to the complexity of medical cases and the inability to co-opt a medical person on the panel. It has been argued that in future it will be difficult for consumer forums to handle the pressure, and consumer redressal forums will soon become clogged and ineffective (*Economic Times* 1995).

In summary, the consumer forums have addressed some of the issues confronting the implementation of COPRA. On the uncertainties and risks inherent in the medical sector, the forums have observed that a doctor needs to establish that he has acted according to approved practice. Understanding the difficulty in where to draw the line between a mistaken diagnosis and negligent behaviour, consumer forums are likely to be guided by a doctor's ability to apply reasonable skills and not whether he exercised the highest degree of skill in a particular situation. The complainants face difficulties in mobilizing expert opinion/support to plead their case as this support has to come from the doctor fraternity. Finally, there are still many legal hassles in terms of whether a case can be tried in the consumer courts. Moreover, the number of cases pending in consumer forums is on the rise.

Part III: Private providers' awareness of COPRA

The previous section discussed various concerns raised by the application of COPRA to private medical practice. This section examines awareness among private providers of the broad objectives of COPRA and discusses the extent to which they think COPRA will be effective in regulating private medical practice.

In India the state and local governments have promulgated a number of regulations to protect the interests of patients. Most of these legislations are drug related. The most important regulation in this category is the Drug Price Control Act which has been effective in keeping drug prices under control. Few legislations address the issues of quality of health care offered by private providers, for example the Nursing Home Act of Bombay and Delhi, and the Consumer Protection Act. We developed a list of the most important legislative Acts and examined the awareness of practising doctors in Ahmedabad, questioning them on the main purposes of these regulations and their effectiveness (see Appendix 1).

Figure 3 presents the results of mailed and interview responses of private doctors in Ahmedabad. It is noteworthy that, of the various regulations, COPRA gets the top score. About 93% of responses indicated awareness of the main objective of the COPRA. In comparison, a majority of respondents indicate low awareness of the main purposes of various other Acts. With the exception of the Indian Medical Council Act, the Medical Council of India – Code of Ethics, the Drugs and Cosmetics Act and the Dangerous Drugs Act, the majority of responses indicate low awareness of other Acts: the Drugs (Price) Control Act, Pharmacy Act, Nursing Homes Acts and Bureau of Indian Standards. In all these cases less than 50% of doctors indicated awareness of their main purposes. One important aspect of COPRA is its applicability nationwide. It does not fall within the category of legislations, such as health legislation, that are state subjects. The high level of awareness of COPRA among practising doctors in Ahmedabad indicates its importance as a legislation affecting private practice in India.

A question about the effectiveness of all these legislations and specifically about COPRA was asked of participants of this survey. Figures 4 and 5 present these findings. Only 11% of respondents think that, overall, these legislations are not effective in protecting the interests of patients. About 76% believe the legislations are moderately to highly effective in protecting the interests of patients. Respondents tended to believe the legislations are effective in protecting patients' interests but raised doubts about their proper enforcement.

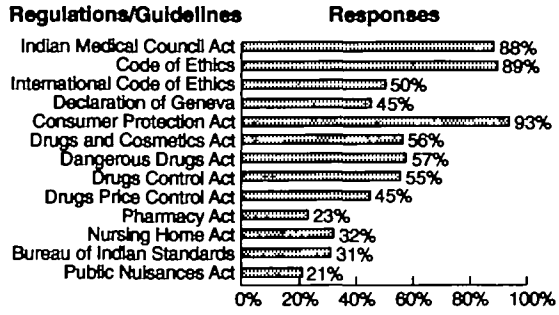

Figure 3. Awareness of various regulations/declarations affecting private practice in India

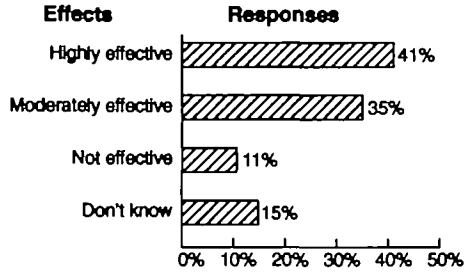

Figure 4. Effectiveness of regulations in protecting the interests of patients

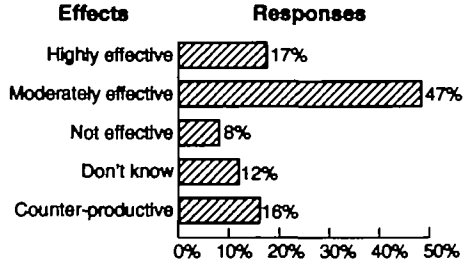

Figure 5. Effectiveness of COPRA in protecting the interests of patients: providers' views

A specific question about the effectiveness of COPRA was asked. About 65% of respondents think that COPRA is effective, moderately to highly, in protecting patient interests. About 16% think that COPRA will be counter-productive to patients. About 12% of respondents were unable to say anything about the effectiveness of this legislation. About 8% believe the COPRA is not at all effective in protecting patient interests.

The inclusion of private medical practice under COPRA is replete with arguments that it will be counterproductive to the interests of patients. The study questionnaire contained questions on effects of COPRA on provider behaviour and on the following aspects of private medical care:

- doctors fee
- cost of diagnostics
- prescription of diagnostic procedures
- prescription of medicines
- time spent with patients
- information provided to patients
- emergency care
- patient awareness

Table 1. The effects of the Consumer Protection Act on various aspects of private practice (mailed responses = 108, and interviewed = 22; all figures in percentages)

Aspects of private practice	Effects				
	Increase significantly	Increase moderately	Remain the same	Decrease moderately	Decrease drastically
Doctors fee	38%	41%	20%	2%	0%
Cost of diagnostics	59%	32%	9%	1%	0%
Prescription of diagnostic procedures	55%	36%	7%	2%	0%
Prescription of medicines	26%	39%	29%	4%	2%
Time spent with each patient	19%	39%	39%	2%	0%
Information given to patients	23%	40%	33%	3%	1%
Emergency care	27%	18%	27%	12%	17%
Patient awareness	36%	44%	17%	2%	2%

Table 1 presents responses of doctors on the effects of COPRA on various aspects of private medical practice. Respondents believe COPRA will significantly increase doctors' fees, with about 79% indicating that the Act will lead to a moderate to significant increase in doctors' fees. Another major concern is the increase in diagnostic charges because of overuse of diagnostic procedures. Over 91% of respondents think that cost of diagnostics and prescription of diagnostics will increase moderately to significantly, and that this will emerge as a major problem of COPRA. About 58% of respondents believe that the implementation of the Act will increase the amount of time a doctor spends with each patient compared to 39% who feel it will not change.

Information is one very important component that can bridge the communication gap between doctor and patient. About 63% of respondents think that COPRA will lead to a moderate to significant increase in information sharing with the patient, whereas 33% foresee no change. Only a small percentage of respondents think that information provided to the patient will decrease.

About 29% of respondents indicated that the implementation of COPRA will lead to a moderate to significant decrease in treating patients needing immediate care. Forty-five per cent think that doctors will pay more attention to treating emergency cases. A large number of doctors, about 80%, think that patient awareness will increase because of COPRA.

In summary, the survey findings reveal that awareness of the broad objectives of COPRA is very high among physicians, with the percentage of respondents in this study being over 90%. The majority of physicians believe the Act will have a desirable effect in protecting the interests of patients and in sharing more information with them. However, this will be at the cost of over-prescription of diagnostic tests, medicines and drugs, and an increase in doctors' fees. These are also some of the reasons for the future increase in health care costs. The view of the effect of COPRA on emergency care is mixed.

Part IV: Policy implications

The legislative judgements regarding the applicability of the Consumer Protection Act, 1986, to the private medical sector are considered an important policy development. This change has been instrumental in recognizing the patient's rights in medical services. It establishes that the patient has a right to question the treatment and procedures in consumer forums if the provider fails to treat the patient as per the

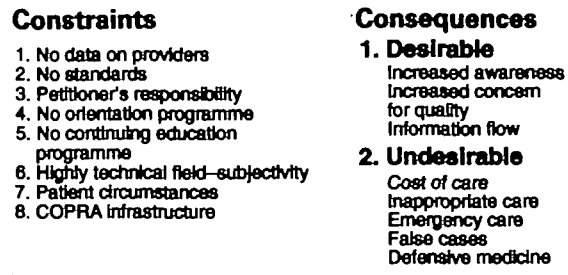

Figure 6. Implementing COPRA: constraints and consequences

standard medical practice or if the provider has not taken adequate care in following accepted standards and, therefore, has been negligent in treating the patient. The previous sections have discussed the recent legislative judgements that have made it possible to bring private medical malpractice cases under the purview of COPRA. The experiences of the last five years in implementing the Act to the medical sector reveal the following:

- Analysis of selected medical negligence cases filed with the National Commission demonstrates that consumer forums at national level recognize the uncertainties and imperfections of the medical sector.
- The medical associations have opposed this development.
- Analysis of cases filed with the CDRC, Gujarat, show that about 71% of cases have gone in favour of doctors.
- Complainants face considerable difficulty in getting experts to defend their cases; the number of cases filed with the CDRC, Gujarat, show that about half of the cases remain pending.
- The private sector institutions lack strong peer pressure, standards for appropriate and general practice, and strong mechanisms to implement existing guidelines.
- Currently there is no provision to identify or penalize complainants filing false cases.

At the same time there are apprehensions that the future of private practice will see a dramatic change as a result of the introduction of COPRA. The direct outcome of COPRA is anticipated to be a growing tendency towards a more defensive medical system among doctors. They are likely to become extremely cautious in treating their patients as COPRA influences their attitudes to risk handling. The implications of this Act are considered to include an increase in the prescription of unnecessary diagnostics and an increase in investigations before treating any patient, resulting in a higher cost of health care.

Given the various undesirable consequences of COPRA, the successful and effective implementation of this Act remains an important issue. There are also a number of constraints under which the Act is being implemented and which may affect its effectiveness for the private medical sector (Figure 6). Policy-makers need to attend to these adverse consequences and constraints in order for the Act to be implemented effectively.

The major constraints (as listed in Figure 6) are: lack of a database on the providers and their practice; lack of adequate standards or comparison of comparative performance; lack of a epidemiological database to determine the risk factors of various disease patterns; lack of a database on risk factors of various diagnostics and procedures; lack of an orientation programme for the doctors; COPRA infrastructure; and absence of an effective continuing education programme.

Making COPRA more effective

The application of COPRA to the private medical sector is just the beginning in ensuring an appropriate quality of care in this sector. However, its implementation has faced problems. For implementation to be successful we need to minimize the undesirable consequences of COPRA. These concerns are pressing and require the urgent attention of policy-makers. Some of the broad recommendations are detailed below.

Firstly, one major problem envisaged is the emergence of a defensive medical culture which will lead to a considerable increase in the cost of care. To overcome this, agencies such as the Indian Medical Council and Association should look at the charge structure for various procedures. Already some concerns have been voiced in Parliament about doctors' fees. The thirteenth report of the upper house of Parliament discusses the arbitrariness in the fee structure of doctors and the lack of transparency in providing information to patients and in financial

matters. The committee has recommended that each doctor should provide the Medical Council of India with a schedule of fee charges, and the Council, in turn, should make this information available to the public. It is recommended that the Medical Council should have responsibility for checking that doctors do not charge higher fees than those notified. The report also contains recommendations on developing a ceiling on doctors' charges.

It is argued that part of the problem of medical negligence and inadequate standards arises from the state structure for entry into the medical profession. It is known that the number of medical colleges has mushroomed and among them private colleges have grown considerably. Admission to these colleges is conditional on the payment of large sums of money. For most of the prospective professionals these funds come from their own sources or from loans. Arguably, this then forces prospective doctors to be more commercially minded, resulting in various undesirable practices which have a significant impact on the quality of care. It has been suggested that an independent Medical Education Commission should be set up to look after, *inter alia*, the finances of and admission to these colleges.

Sometimes newcomers to private practice have little choice because of pressures to earn an adequate return on their capital. New practices also face problems in mobilizing adequate finances at reasonable cost and can end up with a vulnerable mix of loans and borrowed capital. Our survey results show that the interest on capital in these ventures can be as high as 18–22%. Reforms are needed in the financing of private health care providers to ensure them a reasonable cost of capital investment.

Secondly, the Act, at present, has no provision for punishing people who file false cases. There is strong apprehension among providers that the number of false cases will increase and that the legislation will be used for harassing and blackmailing providers. To minimize the misuse of the legislation, the formation of a screening committee has been suggested to review cases before they are formally taken before the consumer forums. The screening committee should also categorize cases in order that only medical negligence cases posing damage or loss to the patient should be pursued further. In cases where the screening committee finds serious problems with the quality of care, the matter should be referred to the medical council. To this end, there should also be a provision for tackling false complaints and the Act should be suitably amended.

Thirdly, most doctors feel that the absence of medical professionals on the panel of councils is a major drawback of the COPRA. Health sector providers were not involved in enacting COPRA nor during later developments in the legislation. It is argued that non-medical people sit in judgement when they are not qualified to make accurate assessments of medical evidence. Thus the suggestion has been made that medical professionals be given greater representation in order that a fair view of medical negligence cases can be obtained.

Finally, there should be an orientation programme for newly graduated doctors who want to start private practice. The adoption of service delivery practices is considerably influenced by the environment in which the newly graduated doctors start practising. From the beginning they adopt the existing practices, most of which are not appropriate. The survey of doctors has shown that the prevalence of practices such as fee-splitting, over-prescription of drugs and diagnostics, inadequate standards, etc., is quite high. To combat this, regular continuing education programmes should be introduced with attendance compulsory. It is well known that a large number of commercial companies send their executives to management development programmes to acquire new skills and to learn of developments in their respective fields. In a large number of companies, promotion policies make it mandatory for executives to attend these programmes. This need not just apply in the commercial sector.

Medical councils and associations have a critical role in these areas. The Medical Council of India should develop a long-term plan of continuing education. This could involve a system whereby membership renewal for providers is conditional upon attendance on the education programmes.

This education role is currently quite effectively played by the drug companies to harness their profit maximizing objectives. This aspect of invisible control by drug companies also needs to be regulated if we want to see a vibrant and effective private medical sector free from the ills of malpractice.

Quality of care remains an important issue

Though the consumer forums recognize that the risk and uncertainty of medical practice is a complicating

factor, this does not extend to all the other complexities of the health care sector. The most important complexity, *inter alia*, is measurement of quality in health care. In the case of consumer goods, comparative information is typically available on the product and its quality. This makes it easier for consumer forums to handle issues of quality in consumer goods. The problems of quality measurement are more profound in the medical sector. The availability of information may partly solve this problem. There is currently little information available in this area as the data collection efforts and comparative performance evaluation of private providers in the health sector are in their infancy.

Besides this, there are other fundamental differences in the way quality is defined in health care compared to other goods and services. Considering the perspectives of government, consumer and provider, Palmer (1993) defines quality of care as 'the production of improved health and satisfaction of a population within the constraints of existing technology, resources, and consumer circumstances'. For this the dimensions which may need measurement are: provider competence (technical components including cognitive, manual and perceptual skills, and interpersonal components), accessibility of care (at the market level and at the beneficiary/consumer level) and acceptability of care (according to the expectations of the individual consumer). The provider is responsible for optimizing these dimensions under three important constraints: limitations of the effectiveness of technology/diagnostics/procedures (i.e. inherent risks); limitations of financial and manpower resources (the given environment); and differences in patient circumstances.

The quality of health care services revolves around these issues. The enactment of COPRA considers the view of the consumer alone. This legislative standalone cannot be effective given the complexities of the health care sector.

Aside from these concerns, the COPRA does not:

- guarantee the implementation of the code;
- ensure the development of standards and concerns for quality;
- provide mechanisms of peer review and peer pressures;
- guarantee that all malpractice cases get reported;
- provide insurance cover for risks in health care.

It is not possible for any single legislation to address wide-ranging concerns and issues in a comprehensive manner. The COPRA is no exception. A comprehensive and integrated mechanism is needed to address the various dimensions of quality in health care and to design an appropriate strategy to deal with the various issues. The preferred way in the long run is to introduce separate, comprehensive legislation. A majority of doctors in our survey also favoured the enactment of separate regulations for the medical profession. Such legislation should be developed after considering the views of government, consumers and providers. The medical associations and councils must be given an appropriate role with responsibility for developing standards and ensuring the availability of information. As discussed earlier, there is no documentation on the general and approved medical practices in India.

To facilitate the development of a data base on private practice, the first step is to implement a separate registration system for all doctors who set up in private practice. At present there is no such system. Their registration is part of the overall system of registering any business establishment. Some structural information, such as types of equipment, location, number of doctors in the practice, numbers of para-medical staff, etc., is not readily available.

We suggest that a separate registration system for private practitioners, with structural information on the establishment, should be mandatory. Without such critical information, the development of norms and standards is impossible. It may also make it impossible to implement quality assurance strategies, such as medical audit and accreditation of health care facilities. The implementation of any programme to improve the quality of care will be considerably constrained by the absence of quality measurement standards. The responsibility for developing a comprehensive information and data base for measuring quality should be entrusted to the medical councils and associations.

Endnotes

[1] In the landmark judgement the Supreme Court in India has upheld the order of the National Commission bringing all private sector health services under the purview of the Consumer Protection Act.

[2] The details of selected medical negligence cases filed with the National Consumers Redressal Commission, New Delhi, from 1989–1993 are available from the author.

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Biography

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Appendix 1. Methodology and sample

A questionnaire was sent to 495 private doctors practising in Ahmedabad city. The doctors were selected randomly from a list of 2920 doctors registered with the Ahmedabad Medical Association (AMA). In total 108 doctors responded to our questionnaire, a response rate of 20%. This was simultaneously followed by in-depth interviews of 22 private doctors. A list of 70 doctors was generated using random selection from the AMA list (excluding the list of 495 doctors selected for the questionnaire study) for this purpose.

The questionnaire consisted of a set of closed-ended questions and a few open-ended questions which pertained to the operational activities of private practitioners and their opinions regarding cost, quality of care and regulatory mechanisms affecting the private medical practice. Before sending the questionnaire, a pilot study was conducted to assess the relevance, clarity of language and content matter of the questionnaire, for which 7 doctors from different disciplines were interviewed. A two-pronged approach of mailed questionnaire and interview was used to check whether the mailed responses contained different responses from the interviews. We report both sets of results. In this section we present only a part of the findings pertaining to COPRA and other legislation and their view on the implications of these changes on private medical practice. Tables A1 and A2 provide the number of years of experience and specialization profile of respondents.

Respondents of both groups, mailed and interview, have varying lengths of experience. About 41% of respondents from the mailed group have less than 10

years experience, compared to a figure of 47% for the interviewed group. About 10% and 14% of the respondents have private practice experience of more than 30 years for the mailed and interviewed groups respectively. A majority of the respondents in both groups are practising as general physicians. The other specializations are represented almost equally in both groups. Over 90% of the respondents in each group are registered as the sole proprietors of their private practice establishment.

Table A1. Number of years in private practice

Number of years	Mailed % (108)	Interviewed % (22)
<5 years	19	5
5≥ 10	22	32
10≥ 20	23	18
20≥ 30	27	36
>30 years	10	14
Total	100	100

Table A2. Specialization profile of respondents

Specialization	Mailed % (108)	Interviewed % (22)
General Physician	42	59
Surgeon	9	5
Anaesthetist	5	5
Paediatrician	7	14
ENT Specialist	2	5
Orthopaedic	5	5
Gynaecologist	8	5
Obstetrician	22	5
Total	100	100