Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-052525
Article Type:	Original research
Date Submitted by the Author:	23-Apr-2021
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Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Nephrology < INTERNAL MEDICINE

Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

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Word count excluding title page, abstract, Summary box, tables & references: 4970

ABSTRACT

Objective:

To explore the accessibility and quality of existing haemodialysis services in an urban setting.

Setting: The study was conducted in Bangalore city, India.

Participants: The study participants included patients, dialysis technicians, duty doctors and nephrologists from twenty dialysis centres in Bangalore city.

Design and methods: Qualitative study using in-depth interviews. A thematic analysis was done using the Availability, Accessibility, Acceptability and Quality Framework (WHO AAAQ) and the Bruce Quality of Care Framework.

Results: The study found several gaps with regards to the access and quality of existing services for CKD patients. The charges for dialysis sessions across settings displayed a wide variance, patients often started dialysis services in private and later shifted to Govt and NGO run centres and reduced the number of weekly dialysis sessions due to financial constraints. Most stand-alone dialysis centres did not have the facilities to manage any emergencies. Most centres did not admit patients with hepatitis or HIV. The quality of care in dialysis centres seemed to be variable and most centres were managed solely by dialysis technicians. There were no psycho-social interventions available to the patients irrespective of the settings. Cost-cutting practices such as employing less qualified technicians, reuse of dialysis equipment, and using substandard water for dialysis were common.

Conclusion: The study points towards the need for improving awareness, and early detection of CKD among urban communities and the need for comprehensive management practices. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better access and quality of existing services.

KEY WORDS

Chronic kidney disease, Access, Quality, Haemodialysis

Strengths and limitations of this study

- The study addresses the research gap on access and quality of exiting dialysis services in a lower middle-income urban setting.
- The study offers a comprehensive perspective on CKD care by including multiple stakeholders perspectives
- Our study demonstrates the applicability of Bruce’s Quality of Care Framework to CKD care.
- We included patients undergoing dialysis for longer term, who represent a small subset of CKD patients

INTRODUCTION

Chronic kidney disease (CKD) has emerged as a major public health challenge worldwide. With a global prevalence of 13.5%(1), it is estimated that about 500 million people suffer from CKD, of which 80% live in LMICs(2). Most LMICs are not equipped to deal with the high burden of CKD; it is often detected at an advanced stage due to the lack of screening programmes, and poor awareness(2),(3). In India, population-based surveys conducted among adults have reported a high prevalence of CKD(4). The Global Burden of Disease Study (2017) reported that there are more than 115 million people with CKD in India(5). CKD can be a complication of many diseases: the most commonly reported risk factors for CKD in India are hypertension and diabetes(6),(7),(8). Though the progression of CKD is usually slow(9), end-stage renal disease (ESRD) patient needs renal replacement therapy (RRT), an artificial process used to remove water, electrolytes and waste substances from the blood (table 1).

Table 1: Definition and classification of CKD(10)

The definition of chronic kidney disease is based on the decreased kidney function (i.e, glomerular filtration rate [GFR]). CKD is classified into five stages based on GFR.

- Stage 1: Kidney damage with normal or increased GFR ≥ 90
- Stage 2: Kidney damage with a mild decrease in GFR (60-89)
- Stage 3: Moderate decrease in GFR (30-59)
- Stage 4: Severe decrease in GFR (15-29)
- Stage 5: Kidney failure (ESRD), the patient requires RRT (GFR < 15)

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Haemodialysis is the most commonly used RRT in India(11). The other options are kidney transplant and peritoneal dialysis, but these are rarely used in the country(12),(13). Haemodialysis uses an artificial kidney (hemodialyzer) to remove waste and extra fluid from the blood. The filtered blood is then returned to the body with the help of a dialysis machine. Once the patient is advised to undergo haemodialysis, a fistula – which is the entry point for haemodialysis – is created between two blood vessels in the patient's arm through a small surgical procedure. Haemodialysis sessions usually last three to five hours. As per the Indian Society of Nephrology guidelines, a patient with CKD is advised to undergo haemodialysis sessions three times a week(14). Along with dialysis, patients need additional medication, supplements and may require blood transfusions. They need to undergo regular laboratory examinations to check for common infections. CKD patients on dialysis are prone to infections, due to their acquired immune deficiency status, frequent hospital admissions and blood transfusions(15). There is a chance of 'machine to patient infection' of blood borne diseases such as hepatitis and HIV during haemodialysis. In India, Hepatitis C Virus infections among patients who undergo dialysis is reported to be high, and infection is one key cause of mortality among dialysis patients in India(16).

Apart from premature mortality, CKD is associated with loss of productivity and high financial burden. In India, facilities that offer haemodialysis in the public sector are limited to tertiary care hospitals situated in district headquarters or cities. Due to this, patients have to depend heavily on the private sector for haemodialysis and other support services, which often results in huge out-of-pocket payments for patients and families(17),(18). As CKD progresses, patients often require emergency admission to hospital for dialysis, which further adds to their financial burden. The charges for a haemodialysis session in India vary from US $13 to 40 (INR 1000- 3000) with additional monthly charges for medicines of about US$ 65-70 (INR 5000)(19). It has been reported that due to financial constraints, only 10% of the end-stage renal disease patients in India receive any renal replacement therapy and of those, >70% die within the first 3 months due to inadequate financial resources to continue therapy (20),(21).

While CKD poses a huge economic burden to patients and families, it also poses significant challenges to health systems(22),(23). Many developed nations spend more than 2–3% of their annual health-care budget for the approximately 0.02-0.03% of patients with ESRD (24). Considering the magnitude of CKD and the financial constraints on patients, the Government of India introduced the Pradhan Mantri National Dialysis Programme in 2016, in which it announced establishing at least one dialysis unit with eight machines in each district to offer free haemodialysis to people living below the poverty line(25). However, India still has less than 2000 nephrologists(26),(11), and 4950 dialysis centres[*], of which 80% operate in the private sector. It is estimated that a centre with ten haemodialysis machines operating three shifts per day can only cater to 60 patients per week. This is not adequate to meet the existing demand for services.

The research on CKD in India has largely focussed on its prevalence, risk factors and treatment costs. There is however a clear knowledge gap on the CKD care process in India: the access to and the quality of the CKD services offered. This requires in-depth qualitative research complementing the quantitative studies cited. The qualitative studies conducted on CKD have so far been limited to either single centre experiences or have offered solo perspectives from either patients or providers. This qualitative study tries to address this research gap by explicitly exploring the access to and the quality of CKD care using multiple stakeholder perspectives, in an urban setting in South India.

METHODS

Study setting

The study was conducted in Bangalore, the capital city of Karnataka State in South India. Bangalore city is part of Bangalore Urban district, which has an area of 2196 sq. kms and has a population of over 9 million(27). There are 104 Primary Health Centres and seven General Hospitals in the Government sector and more than 300 hospitals/nursing homes in the private sector. Bangalore is known for the presence of corporate hospital chains, managed by both national and international players.

Sampling and Data collection

Before the primary data collection, a preliminary mapping of dialysis centres was done by a desktop search, which yielded a result of 88 dialysis centres. From this list, the centres were categorised into three types based on the type of ownership: Private, Government-run and centres run by charitable institutions or Non-Governmental Organisations (NGOs). To get a good

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[*] https://www.expresshealthcare.in/features/breaking-barriers-to-dialysis/277182/

representation of each of these settings, twenty centres were selected purposively for the study, of which 14 were in private, 3 in Government and 3 run by charitable trusts. Basic details of the dialysis centres were captured using a checklist. From these centres, interviews were conducted with a purposively selected consenting sample of patients, dialysis unit technicians, duty doctors, and nephrologists to ensure maximal representation of different stakeholders. These interviews were aimed at capturing their perspectives on the dialysis services including accessibility and quality-related issues. A semi-structured interview schedule based on the World Health Organisation's Availability, Accessibility, Acceptability and Quality (AAAQ) framework(28) and Bruce's Quality of Care framework(29) was used to capture the different aspects of accessibility and quality of dialysis services by different stakeholders. Each interview took about 45-90 mins. The interviews were conducted in the native spoken language Kannada and were later transcribed to English. Table 2 shows the number of participants in each category interviewed.

Table 2: Details of participants interviewed[†]

Participant category	**Type of dialysis facility**			**Total**
	Private	**Government**	**NGO**	
Nephrologists	2	-	-	2
Duty doctors	1	3	3	7
Dialysis technicians	8	3	2	13
Dialysis patients	-	3	3	6
Total				**28**

Data analysis

A thematic analysis was done, using Nvivo (12) qualitative data management software(30). The interview transcripts were imported to Nvivo for coding. After the coding, they were categorised into different themes and subsequently these themes were examined and organised into different components of the WHO AAAQ framework. The quality of care was further categorised as per the Bruce Quality of Care framework. This framework identifies six dimensions of Quality of Care – choice of methods, technical competence, the information given to clients, interpersonal relations, mechanisms to ensure follow-up and continuity, and the appropriate constellation of services.

Ethics

The study protocol was approved by the Ethics Committee for the Social Sciences and Humanities EA SHW- of the University of Antwerp, Belgium (Ref No: SHW_18_82) and permission was taken from the centre authorities before the interviews. Informed consent was taken from the participants. Confidentiality was maintained, all identifying details were removed from the interview transcripts. Authors adhered to the Standards for Reporting Qualitative Research (SRQR), throughout the course of the study(31).

[†] The Government and NGO run dialysis centres did not have any nephrologists present at the time of visit

Patient and Public Involvement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Availability of dialysis services

Most dialysis centres visited were founded in the last 3-6 years. The Government-run dialysis centres were attached to general hospitals and run on Public Private Partnership model, where the facility was located inside Government hospital, but the management was by a third-party agency. While both government and private dialysis centres had 2 to 10 machines, NGO run centres had up to 40 dialysis machines. Most of them offered 3 shifts/day and were open six days a week; at maximum capacity, each machine would thus offer 18 dialysis sessions a week, treating six patients.

The common services offered were haemodialysis along with the supply of medicines/ and other supplements. Only three centres had dietician services. Since the Government centres were located inside a hospital, patients could get the blood examinations done at the same hospital laboratories. A few private centres had laboratories attached. The centres, irrespective of the settings were mostly managed by dialysis technicians and nursing staff, a few centres had duty doctors and visiting nephrologists (once in two weeks or for emergencies). Many interviewees reported that more and more centres were popping up, as the number of patients has increased considerably over the last few years.

Accessibility of dialysis services

Physical accessibility

Most dialysis centres catered to patients coming from a distance of 20-40 km. In the centres run by charitable institutions, a few patients were coming from the nearby districts travelling 3-4 hours for each dialysis session. All centres in the Government and NGO sector had a high patient load and had long waiting lists. Some dialysis centres had to add additional shifts to manage the patient load. A senior technician from a private centre observed:

> *In 1999, we had two dialysis machines and we used to do two shifts, now we have to do daily 4 emergency dialysis, apart from managing the regular patients. Patient numbers have increased, it has become common like a fever. Now we have about 8 machines, and all the machines are occupied, except for the late-night session. (Technician_Private)*

While the private centres had both short term and long-term patients, the Government and NGO run centres reported to have a fixed set of clientele, with most patients coming from the inception of the centre or for a period of 3- 4 years. Only when an existing patient diesd or moveds to another centre, a new admission took place. The technicians in most centres shared that officially the selection of a new patient should be on ‘first come first serve’ basis, but most of the time they were obliged to admit patients coming with references from local politicians. In Government-run centres, patients coming with staff recommendations got priority over the waiting list.

Non-discrimination (accessibility for all patients**)**

The stand-alone dialysis centres did not have the capacity to take care of emergencies, so they didn't admit patients with comorbid heart or lung-related conditions or other complications. Patients who needed emergency care had depended on higher-level centres either in private or government, depending on their financial condition.

> *Here they say that they can't take out more than 3 litres of water [during dialysis], but when I was going to [private centre name], they used to take out 5 litres. And if I get wheezing, then I have to go to another hospital for that. So, I was not coming here.(Patient_Government)*

> *We can't take people with multiple comorbidities or who are in very sick conditions we don't have any facility to take care of emergencies. For example, people with severe cardiac conditions, they can suddenly go into shock or get low BP.(Duty doctor_NGO)*

Only three centres provided dialysis for patients with Hepatitis B, Hepatitis C or HIV, commonly referred by the staff as 'positive patients. All the centres, irrespective of the setting, insisted on a blood test for these three conditions as a prerequisite for admission and if the result was positive, most centres denied admission. According to the staff, it is mainly due to the lack of infrastructure, human resources and cost concerns. The centres catering to patients with these conditions kept one to two machines exclusively for them and allotted a technician only for this section. For such patients, dialyser and other accessories were for single use. For small centres, this is not cost effective, so they did not admit any positive patients.

> *There should be a separate setup for Hepatitis C, B and HIV positive patients. We cannot have the same machines. We have done a separate set up for this, but right now we are not doing it because for positive cases, because the cost is double.(Duty doctor_NGO)*

> *We don't admit seropositive [hepatis B and C, HIV] cases here, not many positive cases come here, we want to make optimum use of the machines, so we don't take them.(Nephrologist_private)*

Economical accessibility (affordability)

All the patients interviewed were from lower to lower-middle socioeconomic status and were availing dialysis services from Government and NGO run centres. All of them were long term dialysis patients and were undergoing dialysis for the last 3-10 years and reported having started their dialysis sessions from private centres and later on shifted to either NGO/Government run centres due to financial constraints. Only one patient was working as an auto driver, all others depended on family members for financial support. Three members reported that they were employed before they were diagnosed with CKD, and they had to leave their jobs due to the illness symptoms and repeated hospitalisations. None of them had any insurance coverage.

In private centres visited, the out-of-pocket expenditure per dialysis session varied between from US$ 11.4 to 42.8* (INR 800 to INR 3000). Government and NGO run centres offered subsidised care; the average cost borne by patients per dialysis session was US$ 5.7-7.1 (INR 400-500) excluding the charges for blood investigations and medications. The technicians reported that approximately 30-40% of their patients had severe anaemia and required additional injections or blood transfusion. They reported that on average, monthly blood investigations would cost US$ 50- 71.4 (INR 3500-5000) in private centres, and US$ 14.2- 21.4 (INR 1000-1500) in charitable centres. Patients with other common comorbid conditions would pay about US$ 500 (INR 35,000) in private centres and about US$ 142.8-171.4 (INR 10,000 to INR 12,000) in Government and NGO- run centres per month. Due to financial constraints, patients often skipped dialysis sessions or shifted from private dialysis centres to either Government or NGO facilities. In the long run, patients often reduced the weekly dialysis sessions and frequency of blood examinations.

> *"I am not able to earn for the last ten years, I had to use all my savings for the treatment, I have spent about 18 Lakhs [US$25,000] so far. I have to pay rent. my wife was not working, after I became a patient, she started going to nearby houses as a domestic help. I started coming here now because I don't have money to go to private." (Patient_Government)*
>
> *"We try to do 3 dialysis [per week] for everyone. But if they cannot bear the cost, then they do 2 dialysis. They do this to save 300-400 rupees a week, but if they get into any complication [because they skipped dialysis], then they will end up spending 30 to 40 thousand rupees to manage that". (Duty Doctor_Private)*

Quality of care

The key findings related to the quality of dialysis services are organised below, using the six dimensions stipulated in the Bruce quality of care framework.

Choice of methods

Haemodialysis was the only renal replacement therapy provided in most of the centres, one private centre has started with kidney transplants. None of the visited centres provided Peritoneal Dialysis (PD). The technicians shared that though they have learned about PD and its advantages, they never practised it. According to them, in the Indian context, it is difficult for patients to opt for PD because the surroundings need to be kept sterile and clean while most patients do not have enough resources for that. None of the interviewed patients was given PD as a treatment option and they were not aware of the PD process. None of them had registered for renal transplant.

> *"I have spoken to doctors abroad, there they prefer Peritoneal Dialysis, here we don't do it because here patient can't afford to have a separate room for it, also the fluid they use is very expensive here, it could be because only a few people are using it"(Technician_NGO)*

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* INR to USD calculated at the conversion rate of 70.

Information given to clients

Patients reported that they did not have any prior knowledge of CKD, its symptoms or management before they were diagnosed. All of them were caught unaware of kidney failure as a complication of diabetes or hypertension and were subsequently advised to undergo haemodialysis. Technicians reported that most patients came with kidney failure because of undetected hypertension or diabetes. Patients reported that they learned about the complications of dialysis, diet and weight management over the years, and tried to manage complications at home to the extent possible.

> "*I had BP [Hypertension]. I was not taking medicine. I neglected. I didn't know it will lead to this type of problem [kidney disease]."(Patient_NGO)*

> *"If I get a breathing problem, I put 4 or 5 pillows and lean on it, switch on the fan, I try to control it like that. I don't have money to go to ICU suddenly. One more problem is- I have dialysis on Tuesday, Thursday and Saturday. There will be 2 days gap after Saturday, so the quantity of water increases in the body and it leads to breathing difficulty. So, I reduce the consumption of food at that time, to reduce the breathing problem."(Patient_Govt).*

Interpersonal relations

Most dialysis centres provided dialysis in open wards, with beds next to each other. Since most patients had fixed days and timing for dialysis, they saw and interacted with the same set of fellow patients. Patients shared their experiences and learned from their peers about managing the symptoms. A duty doctor in a Govt centre observed that having open wards helped in reducing patient anxiety regarding the dialysis process.

> *"I think open wards are good, even screen between patients are not necessary. If there is screen and if we are attending a patient [with complication], other patients think, we are doing something to the patient and start worrying. If it is open, then they can see openly what we are doing and what we are telling. They will know there is nothing serious*."(Duty doctor_NGO)

Mechanisms to ensure follow-up and continuity

Technicians and duty doctors from the NGO run centres reported that patients usually did not miss dialysis sessions since it was free or subsidised. Centres having laboratory attached to them had a fixed day of the month when they did the routine examinations. Patients were advised not to travel for more than two days, in order not to miss dialysis. When patients had to travel to far-off places or for longer duration, they had to enrol in a local dialysis centre. Staff shared that this is one common reason for infections.

> *Some patients travel to their home town or relatives houses for some festivals or family functions, if they go for more than two days, they have to get the dialysis done, they will go to some local place and get it done, once they come back and when we do*

> *the blood test, we find that they have become positive for Hepatitis B or C. (Techinican_Private).*

All centres maintained patient records. A few centres had detailed case notes including previous treatment details, lab reports, and other clinical parameters, others kept only patient contact details along with the blood pressure readings and weight on the day of dialysis.

Appropriate constellation of services

The dialysis centres in the private sector had better infrastructure, separate beds and screens or curtains between the beds. Govt and NGO centres provided the services in open wards, with beds next to each other. There was no separation between male and female wards in most of the centres. From the dialysis centres visited, three centres in the private sector had a dietician who provided diet counselling to the newly admitted patients. Patients undergoing dialysis under Government centres often faced a shortage of required medicines and supplements, where the medicines are supplied free of cost. Due to this, they had to spend money on purchasing medicines from private pharmacies.

> *"Because medicines were not available, many times I have gone to other places to get it. Even last month I had gone to another centre. We complained to the Medical Officer last month and after that, there is no problem.": (Patient_Government)*

While it was noted that patients often felt helpless and hopeless thinking about the treatment expenses and the prognosis of their illness, none of the visited dialysis centres had any counsellors or social workers offering counselling or any other psychosocial support to patients.

> *"All your money will all be spent [for the treatment]. If you go inside the ICU once, you will need a minimum of 50000 rupees. It has been very difficult for me, I have even thought of committing suicide, what else can be done? (Patient_NGO)*

> *"We spent a lot of money for the treatment. Now we have nothing left but for this illness. We can't eat or even drink water, we may die soon too. We lose self-confidence and start to feel we are not normal, and sometimes think why to live like this." (Patient_Government)*

Technical competence

All the visited centres, irrespective of the sectors, were mainly managed by dialysis technicians. A few of them had duty doctors, only two centres had the presence of a nephrologist in the premises. In most centres, one or two technicians managed the centres with 7-10 patients in a single shift. They reported that there are 6 months to one-year dialysis technician courses available and such courses do not equip the technicians to notice complications during dialysis.

> *In many centres there are no nephrologists, and there are unqualified technicians, they may not even know how to read and write properly, but they will be doing*

> *dialysis. They just know how to switch on and off the machine, nothing else. (Nephrologist_private)*

> *Private dialysis centres have less qualified technicians to cut cost. They may not practice safety precautions while handling of the dialyzer and other equipments which would lead to infections and other complications. Patients won't know what is happening. (Technician_Government)*

In some centres, the same technicians handle patients with and without infections such as Hepatitis and HIV, this coupled with their lack of adequate training puts patients at risk for infections. Other cost cutting practices reported were the use of sub-standard water purifiers, and other equipment including dialysers and tubes. These practices led to patients getting infections and having other complications during dialysis. Most centres used a dialyser for ten dialysis sessions and a few centres reused the tubes as well. The technicians shared that if the machine parts were not cleaned with strict safety precautions , 'machine to patient infections' could happen. Technicians and duty doctors reported that they commonly saw infections such as Hepatitis C (HCV) and Hepatitis B (HBV) among patients. Staff from a few dialysis centres mentioned that they did not admit patients referred from certain centres due to the fear of transmission.

> *"People with Kidney Disease are prone to get Hepatitis C and many hospitals are spreading it like anything. Some hospitals, I can name them, they are harbouring this and spreading. Patients coming from certain hospitals, we know that they will be positive, we know that their quality of treatment is poor".(Duty doctor_NGO)*

> *You can get water treatment plants for 200,000 rupees or for 20 million rupees. That's the main area to cut costs. For each dialysis session, you need about a hundred litres of water and the quality of water will definitely affect the dialysis outcome. While there are standards, they are not legal requirements. Standards are not laws, so even if you don't follow the standards, nothing will happen, no one will question. (Nephrologist_Private)*

DISCUSSION

This study throws light on the landscape of dialysis services offered in an urban setting in South India, and poses a few important questions on the accessibility, and quality of existing services. While it appears that the availability of haemodialysis services may not be a serious issue, economic access is a major challenge. Although dialysis services are predominantly offered by the private sector, the wide variability in charges for dialysis and support services renders them inaccessible for large groups of patients. Though the centres in the Government and NGO settings charge much less per session, patients from poorer families still do not have sufficient resources to afford these. Also, such centres are too few in numbers to be able to cater to the rising demand for dialysis services. Our findings showed that due to financial constraints, patients are often forced to skip dialysis sessions. Similar findings were reported earlier by V Jha (2013)(32) and Karopady et al (2013)(33). Another study conducted by Gunjeet Kaur et al (2018) found the prevalence of

Catastrophic Health Expenditure (CHE) to be as high as 51% among patients undergoing haemodialysis thrice a week(34).

In India, diabetes and hypertension are the key causative factors for CKD and these conditions make patients prone to complications during dialysis. Earlier studies have reported that hypotension, nausea and vomiting are commonly reported during dialysis, our study too showed similar findings(35). While infections, especially HCV and HBV are commonly reported in the CKD population due to frequent dialysis and blood transfusions, the number of centres catering to patients with these conditions are very limited. Patients with any comorbid conditions and other complications have to depend on centres with emergency facilities, which in turn increases the cost, as most of them are attached to major private hospitals. So, patients end up shuttling between centres in different settings depending on their illness status and paying capacity.

The study findings raise important questions regarding the overall quality of dialysis services across settings. The cost cutting practices including using substandard equipment, and reuse of dialysers compromise the quality of dialysis. While earlier studies have shown that the quality of the dialyser and water used for dialysis are important predictors for better patient outcomes(36), our study showed that the water treatment plants are available at varying costs and currently there are no mechanisms to ensure the water quality. While most of the centres are managed solely by dialysis technicians, the quality of their training seems to be variable. If technicians would be capable of identifying the early warning signs, many of the complications could be averted, including problems with fistula(37).

Though the benefits of peritoneal dialysis is well documented(38), our findings show that it is still not accessible to patients with CKD. Acknowledging this, the Government of India published a set of guidelines for states for starting peritoneal dialysis facilities as part of the Pradhan Mantri National Dialysis Programme(39). It provides the necessary guidance for the states to set up peritoneal dialysis centres, and serve as a best practice document for providers of peritoneal dialysis and thus ensuring delivery of high quality, cost effective CAPD services. While it is a welcome move, states will have to implement it in an effective and timely manner.

CKD is known to be associated with various psychological issues such as depression, anxiety, and poor quality of life. A multi-centre study conducted in India found that depression was common among haemodialysis patients and long-term dialysis and poverty status had a significant relationship with depression(40). Another study conducted among CKD patients from Karnataka reported depression to be more common in patients on dialysis compared to other modalities of treatment(41). While supportive interventions have been found to be effective among patients with CKD(42), our findings indicate that the existing services do not cater to the psychosocial needs of the patients. Having the services of a trained counsellor or a social worker available in these centres would give the patients an opportunity to discusses their psychosocial problems, which could potentially help in reducing their emotional discomfort during the dialysis process and improve overall treatment outcome. Earlier studies have reported a positive effect of counselling on patients with CKD(43).

Limitations of the study

While the study provides a snapshot of the dialysis services provided in an urban setting in India, it is subject to certain limitations. The study took place in a selection of CKD care facilities in an urban setting in India and the results might therefore not necessarily be generalizable to other settings. The study respondents were undergoing dialysis for longer term, and we acknowledge that they represent a small subset of CKD patients. Due to the difficulty in obtaining necessary approvals from the authorities, patients undergoing dialysis services from the private sector could not be included in the study sample.

Implications of the study and future directions

By including multiple stakeholders, our study offers a comprehensive perspective on CKD care in a lower middle-income urban setting. It also demonstrates the applicability of Bruce's Quality of Care Framework to CKD care. The study points towards the need for improving awareness, and early detection of CKD among urban communities and the need for comprehensive management practices, including diet counselling and psychosocial support. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better access and quality of existing services. With the increasing burden of CKD in India, more in-depth studies are needed exploring patient experiences at different stages of their illness, which would help in designing appropriate interventions at each stage of CKD.

Contributorship statement

MAE conceptualised the study, in consultation with WVD and EW. MAE collected the data, conducted the first level of analysis, and prepared the first draft of the manuscript. WVD contributed to the study design, data analysis and writing the manuscript. EW contributed to data analysis and writing the manuscript. All three authors participated in data analysis discussions, revision of the manuscript and concurred on the final draft of the manuscript. All authors met the ICMJE criteria for authorship.

Competing interests

None to be declared

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article

Data sharing statement

Data can be made available on reasonable request

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Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

Page/line no(s).

Title and abstract

Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	1

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	1-2
Purpose or research question - Purpose of the study and specific objectives or questions	3

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	3
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	-
Context - Setting/site and salient contextual factors; rationale**	3
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	3
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	4
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	3-4

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	3-4
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	3-4
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	3-4
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	3-4
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	3-4

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	4-10
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	4-10

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	10-11
Limitations - Trustworthiness and limitations of findings	11

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	NA
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	NA

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014 DOI: 10.1097/ACM.0000000000000388

Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-052525.R1
Article Type:	Original research
Date Submitted by the Author:	16-Sep-2021
Complete List of Authors:	Elias, Maya ; University of Antwerp, Department of Sociology Van Damme, Wim; Institute of Tropical Medicine, Public Health Wouters, Edwin; University of Antwerp, Department of Sociology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Health policy, Health services research, Qualitative research
Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Chronic renal failure < NEPHROLOGY

Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

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Word count excluding title page, abstract, Summary box, tables & references: 5078

ABSTRACT

Objective: To explore the accessibility and quality of existing haemodialysis services in an urban setting.

Setting: The study was conducted in Bangalore city, India.

Participants: A total of 28 stakeholders including 2 nephrologists, 7 duty doctors, 13 dialysis technicians and 6 patients on long term haemodialysis selected from twenty dialysis centres in Bangalore city.

Design and methods: Qualitative study using in-depth interviews. A thematic analysis was done using the Availability, Accessibility, Acceptability and Quality Framework of World Health Orgnization (WHO AAAQ) and the Bruce Quality of Care Framework.

Results: The study found several gaps with regards to the access and quality of existing services for End Stage Renal Disease patients. The charges for dialysis sessions across settings displayed a wide variance, patients often started dialysis services in private and later shifted to Government and Non-Governmental Organisations run centres and reduced the number of weekly dialysis sessions due to financial constraints. Most stand-alone dialysis centres did not have the facilities to manage any emergencies. Most centres did not admit patients with hepatitis or HIV. The quality of care in dialysis centres seemed to be variable and most centres were managed solely by dialysis technicians. There were no psycho-social interventions available to the patients irrespective of the settings. Cost-cutting practices such as employing less qualified technicians, reuse of dialysis equipment, and using substandard water for dialysis were common.

Conclusion: The study highlights the need for more financial and personnel investments in ESKD care in India to ensure optimal care for the growing patient population. The study points towards the need for comprehensive management practices, including diet counselling and psychosocial support. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better access and quality of existing services.

KEY WORDS

End Stage Renal Disease, Access, Quality, Haemodialysis

Strengths and limitations of this study

- The study addresses the dearth of knowledge on the accessibility and quality of existing haemodialysis services in a lower middle-income urban setting.

- The study offers a comprehensive perspective on dialysis care by including multiple stakeholders' perspectives.
- Our study demonstrates the applicability of Bruce's Quality of Care Framework to dialysis care.
- Patients undergoing dialysis services from the private sector could not be included in the study sample.
- We included patients undergoing dialysis for longer term, who represent a small subset of ESRD patients, the results might therefore not necessarily be generalizable to the whole spectrum of ESRD care.

INTRODUCTION

Chronic kidney disease (CKD) has emerged as a major public health challenge worldwide. With a global prevalence of 13.5%(1), it is estimated that approximately 500 million people suffer from CKD, of which 80% live in Low and Middle Income Countries (LMIC)(2). Most LMICs are not equipped to deal with the high burden of CKD; it is often detected at an advanced stage due to the lack of screening programmes, and poor awareness(2),(3). In India, population-based surveys conducted among adults have reported a high prevalence of CKD(4). The Global Burden of Disease Study (2017) reported that there are more than 115 million people with CKD in India(5). CKD can be a complication of many diseases: the most commonly reported risk factors for CKD in India are hypertension and diabetes(6),(7),(8).

Though the progression of CKD is usually slow(9), end-stage renal disease (ESRD) patient needs renal replacement therapy (RRT), an artificial process used to remove water, electrolytes and waste substances from the blood. Haemodialysis is the most commonly used RRT in India(10). The other options are kidney transplant and peritoneal dialysis, but these are rarely used in the country(11),(12). Haemodialysis uses an artificial kidney (hemodialyzer) to remove waste and extra fluid from the blood. The filtered blood is then returned to the body with the help of a dialysis machine.

Once the patient is advised to undergo haemodialysis, a central venous catheter or an arteriovenous fistula is created as an entry point for haemodialysis. To insert the central venous catheter, a small incision is made in the skin over the selected vein located in the neck, upper chest, or groin. The fistula is created between two blood vessels in the patient's arm through a small surgical procedure. In India, most patients undergo emergency haemodialysis(13), a line access using a catheter is created and later patients are advised to switch to the arteriovenous fistula. Haemodialysis sessions usually last three to five hours. As per the Indian Society of

Nephrology guidelines, a patient with ESRD is advised to undergo haemodialysis sessions three times a week(14). Along with dialysis, patients need medication, supplements and may require blood transfusions. They need to undergo regular laboratory examinations to check for common infections. ESRD patients on dialysis are prone to infections, due to their acquired immune deficiency status, frequent hospital admissions and blood transfusions(15). There is a chance of ‘machine to patient infection’ of blood borne diseases such as hepatitis and HIV during haemodialysis. In India, Hepatitis C Virus infections among patients who undergo dialysis is reported to be high, and infection is one key cause of mortality among dialysis patients in India(16).

Apart from premature mortality, ESRD is associated with loss of productivity and high financial burden. In India, facilities that offer haemodialysis in the public sector are limited to tertiary care hospitals situated in district headquarters or cities. Due to this, patients have to depend heavily on the private sector for haemodialysis and other support services, which often results in huge out-of-pocket payments for patients and families(17),(18). Patients with ESRD often require emergency admission to hospital for dialysis, which further adds to their financial burden. The charges for a haemodialysis session in India vary from US $13 to 40 (INR* 1000-3000) with additional monthly charges for medicines of about US$ 65-70 (INR 5000)(19). It has been reported that due to financial constraints, only 10% of the end-stage renal disease patients in India receive any renal replacement therapy and of those, >70% die within the first 3 months due to inadequate financial resources to continue therapy(20),(21).

While ESRD poses a huge economic burden to patients and families, it also poses significant challenges to health systems(22),(23). Many developed nations spend more than 2–3% of their annual health-care budget for the approximately 0.02-0.03% of patients with ESRD (24). Considering the magnitude of ESRD and the financial constraints on patients, the Government of India introduced the Pradhan Mantri National Dialysis Programme in 2016, in which it announced establishing at least one dialysis unit with eight machines in each district to offer free haemodialysis to people living below the poverty line(25). However, India still has less than 2000 nephrologists(26),(10), and 4950 dialysis centres†, of which 80% operate in the private sector. It is estimated that a centre with ten haemodialysis machines operating three shifts per day can only cater to 60 patients per week. This is not adequate to meet the existing demand for services.

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* INR stands for Indian Rupee. One USD is approximately around INR 70.

† https://www.expresshealthcare.in/features/breaking-barriers-to-dialysis/277182/

The research on ESRD in India has largely focussed on its prevalence, risk factors and treatment costs(5), (6),(19). There is however a clear knowledge gap on the ESRD care process in India: the access to and the quality of the services offered. This requires in-depth qualitative research complementing the quantitative studies cited. The qualitative studies conducted on ESRD have so far been limited to either single centre experiences or have offered solo perspectives from either patients or providers. This qualitative study tries to address this research gap by explicitly exploring the access to and the quality of ESRD care using multiple stakeholder perspectives, in an urban setting in South India.

METHODS

Study Design

With an objective of producing in-depth knowledge on the accessibility and quality of dialysis care in India, a qualitative research design (using thematic analysis) was employed for the study.

Study setting

The study was conducted in Bangalore, the capital city of Karnataka State in South India. Bangalore city is part of Bangalore Urban district, which has an area of 2196 sq. kms and has a population of over 9 million(27). There are 104 Primary Health Centres and seven General Hospitals in the Government sector and more than 300 hospitals/nursing homes in the private sector. Bangalore is known for the presence of corporate hospital chains, managed by both national and international players.

Sampling and Data collection

Before the primary data collection, a preliminary mapping of dialysis centres was done by a desktop search, which yielded a result of 88 dialysis centres. From this list, the centres were categorised into three types based on the type of ownership: Private, Government-run and centres run by charitable institutions or Non-Governmental Organisations (NGOs). To get a good representation of each of these settings, twenty centres were selected purposively for the study, of which 14 were in the private, 3 in the Government sector and 3 were run by charitable trusts. Basic details of the dialysis centres were captured using a checklist(details captured attached as supplementary file 1). From these centres, interviews were conducted with a purposively selected consenting sample of patients, dialysis unit technicians, duty doctors, and nephrologists to ensure maximal representation of different stakeholders. These interviews were aimed at capturing their perspectives on the dialysis services including accessibility and quality-related issues. A semi-structured interview schedule based on the World Health

Organisation's Availability, Accessibility, Acceptability and Quality (AAAQ) framework(supplementary file 2)(28) and Bruce's Quality of Care framework(supplementary file 3)(29) was used to capture the different aspects of accessibility and quality of dialysis services by different stakeholders. These interviews were conducted between September to December 2020 by the first author, who is an experienced qualitative researcher. Each interview took about 45-60 mins (interview topic guide attached as supplementary file 4). The interviews were conducted in the native spoken language Kannada and were later transcribed to English. Table 1 shows the number of participants in each category interviewed.

Table 1: Details of participants interviewed‡

Participant category	**Type of dialysis facility**			**Total**
	Private	**Government**	**NGO**	
Nephrologists	2	-	-	2
Duty doctors§	1	3	3	7
Dialysis technicians	8	3	2	13
Dialysis patients	-	3	3	6
Total				**28**

Data analysis

A thematic analysis was done, using Nvivo (12) qualitative data management software(30). The interview transcripts were imported to Nvivo for coding. After the coding, they were categorised into different themes and subsequently these themes were examined and organised into different components of the WHO AAAQ framework. The quality of care was further categorised as per the Bruce Quality of Care framework. This framework identifies six dimensions of Quality of Care – choice of methods, technical competence, the information given to clients, interpersonal relations, mechanisms to ensure follow-up and continuity, and the appropriate constellation of services.

Ethics

The study protocol was approved by the Ethics Committee for the Social Sciences and Humanities EA SHW- of the University of Antwerp, Belgium (Ref No: SHW_18_82) and

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‡ The Government and NGO run dialysis centres did not have any nephrologists present at the time of visit

§ A medical officer on duty, who is an MBBS graduate, the National Dialysis programme stipulates the presence of one duty doctor for ten patients.

permission was taken from the centre authorities before the interviews. Informed consent was taken from the participants. Confidentiality was maintained, all identifying details were removed from the interview transcripts. Authors adhered to the Standards for Reporting Qualitative Research (SRQR), throughout the course of the study(31).

Patient and Public Involvement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Availability of dialysis services

Most dialysis centres visited were founded in the last 3-6 years. The Government-run dialysis centres were attached to general hospitals and run on Public Private Partnership model, where the facility was located inside Government hospital, but the management was by a third-party agency. While both government and private dialysis centres had 2 to 10 machines, NGO run centres had up to 40 dialysis machines. Most of them 3 shifts/day and were open six days a week (which at maximum capacity equals 18 dialysis treatment sessions per week, supporting a 3x per week prescription for up to 6 patients).

The common services include haemodialysis supply of medicines/ and other nutritional supplements. Only three private centres had dietician services available. Since the Government centres were located inside a hospital, patients could get the blood examinations done at the same hospital laboratories. Six private dialysis centres which were attached to bigger hospitals had laboratory facilities in the premises. The centres, irrespective of the settings were mostly managed by dialysis technicians and nursing staff; duty doctors were present in seven private centres, two Government centres and one NGO centre. Only two centres in private had nephrologists at the time of visit, other centres reported that they have a visiting nephrologist, who is 'on call'.

Accessibility of dialysis services

Physical accessibility

All dialysis centres catered to patients coming from a distance of 20-40 km. In the centres run by charitable institutions, a few patients were coming from the nearby districts travelling 3-4 hours for each dialysis session. All centres in the Government and NGO sector were run at full capacity. Technicians across settings reported of increase in patient numbers over the years. Technicians from four dialysis centres in private and 2 centres in NGO sector reported of starting additional shifts in the last two years. A senior technician from a private centre observed:

> *In 1999, we had two dialysis machines and we used to do two shifts, now we have to do daily 4 emergency dialysis, apart from managing the regular patients. Patient numbers have increased, it has become common like a fever. Now we have about 8 machines, and all the machines are occupied, except for the late-night session. (Technician_Private)*

> *Stand-alone centres do three shifts usually, centres part of larger chains such as [centre name], have started night shifts too. The Government run centres usually do not have enough manpower and other supplies to run extra shifts. (Nephrologist_Private)*

While the private centres had both short term and long-term patients, the Government and NGO run centres reported to have a fixed set of clientele, with most patients coming from the inception of the centre or for a period of 3- 4 years. Only when an existing patient died or moved to another centre, a new admission took place. While the private centres received occasional enquiries of new patients, all Government and NGO run centres visited had more than ten patients waiting to be enrolled, and the waiting period was approximately between three to six months. When there was a vacancy, patients coming with staff or local political leaders' recommendations were given priority for admission.

***Non-discrimination (accessibility for all patients*)**

Only three centres provided dialysis for patients with Hepatitis B, Hepatitis C or HIV, commonly referred by the staff as 'positive patients. All the centres, irrespective of the setting, insisted on a blood test for these three conditions as a prerequisite for admission and if the result was positive, most centres denied admission. According to the staff, it is mainly due to the lack of infrastructure, human resources, and cost concerns. The centres catering to patients with these conditions kept one to two machines exclusively for them and allotted a technician only for this section. For such patients, dialyser and other accessories were for single use. For small centres, this is not cost effective, so they did not admit any positive patients.

> *There should be a separate setup for Hepatitis C, B and HIV positive patients. We cannot have the same machines. We have done a separate set up for this, but right now we are not doing it because for positive cases, because the cost is double.(Duty doctor_NGO)*

> *We don't admit seropositive [hepatis B and C, HIV] cases here, not many positive cases come here, we want to make optimum use of the machines, so we don't take them.(Nephrologist_private)*

The stand-alone dialysis centres did not have the capacity to take care of emergencies, so they didn't admit patients with comorbid heart or lung-related conditions or other complications. Patients who needed emergency care had to depend on higher-level centres.

Economical accessibility (affordability)

All the patients interviewed were from lower to lower-middle socioeconomic status and were availing dialysis services from Government and NGO run centres. All of them were long term dialysis patients and were undergoing dialysis for the last 3-10 years and reported having started their dialysis sessions from private centres and later shifted to either NGO/Government run centres due to financial constraints. Only one patient was working as an auto driver, all others depended on family members for financial support. Three members reported that they were employed before they were diagnosed with ESRD, and they had to leave their jobs due to the illness symptoms and repeated hospitalisations. None of them had any insurance coverage.

In private centres visited, the out-of-pocket expenditure per dialysis session varied between from US$ 11.4 to 42.8* (INR 800 to INR 3000). Government and NGO run centres offered subsidised care; the average cost borne by patients per dialysis session was US$ 5.7-7.1 (INR 400-500) excluding the charges for blood investigations and medications. The technicians reported that approximately 30-40% of their patients had severe anaemia and required additional injections or blood transfusion. They reported that on average, monthly blood investigations would cost US$ 50- 71.4 (INR 3500-5000) in private centres, and US$ 14.2-21.4 (INR 1000-1500) in charitable centres. Patients with other common comorbid conditions would pay about US$ 500 (INR 35,000) in private centres and about US$ 142.8-171.4 (INR 10,000 to INR 12,000) in Government and NGO- run centres per month. Due to financial constraints, patients often skipped dialysis sessions or shifted from private dialysis centres to either Government or NGO facilities. In the long run, patients often reduced the weekly dialysis sessions and frequency of blood examinations.

> *I am not able to earn for the last ten years, I had to use all my savings for the treatment, I have spent about 18 Lakhs [US$25,000] so far. I have to pay rent. my wife was not working, after I became a patient, she started going to nearby houses as a domestic help. I started coming here now because I don't have money to go to private. (Patient_Government)*

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* INR to USD calculated at the conversion rate of 70.

> *We try to do 3 dialysis [per week] for everyone. But if they cannot bear the cost, then they do 2 dialysis. They do this to save 300-400 rupees a week, but if they get into any complication [because they skipped dialysis], then they will end up spending 30 to 40 thousand rupees to manage that. (Duty Doctor_Private)*

Quality of care

The key findings related to the quality of dialysis services are organised below, using the six dimensions stipulated in the Bruce quality of care framework.

Choice of methods

Haemodialysis was the only renal replacement therapy provided, except for one private centre which offered kidney transplants. None of the visited centres provided Peritoneal Dialysis (PD). The technicians shared that though they have learned about PD and its advantages, they never practised it. According to them, in the Indian context, it is difficult for patients to opt for PD because the surroundings need to be kept sterile and clean while most patients do not have enough resources for that. None of the interviewed patients was given PD as a treatment option and they were not aware of the PD process. None of them had registered for renal transplant.

> *I have spoken to doctors abroad, there they prefer Peritoneal Dialysis, here we don't do it because here patient can't afford to have a separate room for it, also the fluid they use is very expensive here, it could be because only a few people are using it. (Technician_NGO)*

> *PD has to be done 27/7, and here it is not very practical, also you need the presence of someone to assist. Patients housing and other conditions are not very suitable for PD in our setting. So, PD is slowly going out of practice here (Nephrologist, private)*

Information given to clients

Patients reported that they did not have any prior knowledge of ESRD, its symptoms or management before they were diagnosed. All of them were caught unaware of kidney failure as a complication of diabetes or hypertension and were subsequently advised to undergo haemodialysis. Nephrologists and technicians reported that most patients came with kidney failure because of undetected hypertension or diabetes. Patients reported that they learned about the complications of dialysis, diet, and weight management over the years, and tried to manage complications at home to the extent possible.

> *I had BP [Hypertension]. I was not taking medicine. I neglected. I didn't know it will lead to this type of problem [kidney disease]. (Patient_NGO)*

> *Most patients will present with symptoms of renal failure, and when we do the examinations, many will have uncontrolled diabetes or hypertension. When we ask the*

> *patients why they did not take medicines, they say we did not know. (Nephrologist, private)*

Interpersonal relations

All dialysis centres provided dialysis in open wards, with beds next to each other. Since most patients had fixed days and timing for dialysis, they saw and interacted with the same set of fellow patients. Patients shared their experiences and learned from their peers about managing the symptoms. A duty doctor in a Govt centre observed that having open wards helped in reducing patient anxiety regarding the dialysis process.

> *I think open wards are good, even screen between patients are not necessary. If there is screen and if we are attending a patient [with complication], other patients think, we are doing something to the patient and start worrying. If it is open, then they can see openly what we are doing and what we are telling. They will know there is nothing serious*.(Duty doctor_NGO)

A nephrologist observed that in Government and NGO run centres, patients had more opportunities to interact with other patients, and in Private centres, most patients would arrive at their fixed timing for the dialysis and their interactions are usually limited to the staff and maximum to the patients who occupy the next bed.

Mechanisms to ensure follow-up and continuity

Technicians and duty doctors from the NGO run centres reported that patients regularly attended their scheduled dialysis sessions, since it was free or subsidised. Patients were advised not to travel for more than two days. When patients had to travel to far-off places or for longer duration, either they must skip a scheduled dialysis, or they must enrol in a local dialysis centre. Staff shared that this is one common reason for infections.

> *Some patients travel to their hometown or relatives houses for some festivals or family functions, if they go for more than two days, they have to get the dialysis done, they will go to some local place and get it done, once they come back and when we do the blood test, we find that they have become positive for Hepatitis B or C. (Techinician_Private).*

All centres maintained patient records. A few centres had detailed case notes including previous treatment details, lab reports, and other clinical parameters, others kept only patient contact details along with the blood pressure readings and weight on the day of dialysis.

Appropriate constellation of services

The dialysis centres in the private sector had better infrastructure, separate beds and screens or curtains between the beds. Govt and NGO centres provided the services in open wards, with beds next to each other. There was no separation between male and female wards in most of the centres. From the dialysis centres visited, three centres in the private sector had a dietician who provided diet counselling to the newly admitted patients. Patients undergoing dialysis under Government centres often faced a shortage of required medicines and supplements, where the medicines are supplied free of cost. Due to this, they had to spend money on purchasing medicines from private pharmacies.

> *Because medicines were not available, many times I have gone to other places to get it. Even last month I had gone to another centre. We complained to the Medical Officer last month and after that, there is no problem."(Patient_Government)*

While it was noted that patients often felt helpless and hopeless thinking about the treatment expenses and the prognosis of their illness, none of the visited dialysis centres had any counsellors or social workers offering counselling or any other psychosocial support to patients.

> *All your money will all be spent [for the treatment]. If you go inside the ICU once, you will need a minimum of 50000 rupees. It has been very difficult for me, I have even thought of committing suicide, what else can be done? (Patient_NGO)*
>
> *I have not seen a counsellor in any dialysis centre. In India, we don't have the concept of a counsellor, the doctors only talk to the patients. There is an issue of time constraint, we may not enough time to talk to everyone. (Nephrologist, private)*

Technical competence

All the visited centres, irrespective of the sectors, were mainly managed by dialysis technicians. Seven centres had duty doctors, only two centres had full time nephrologists. In all visited centres, one or two technicians managed the centres with 7-10 patients in a single shift. They reported that there are 6 months to one-year dialysis technician courses available and such courses do not equip the technicians to notice complications during dialysis.

> *In many centres there are no nephrologists, and there are unqualified technicians, they may not even know how to read and write properly, but they will be doing dialysis. They just know how to switch on and off the machine, nothing else. (Nephrologist_private)*
>
> *Private dialysis centres have less qualified technicians to cut cost. They may not practice safety precautions while handling of the dialyzer and other equipments which*

> *would lead to infections and other complications. Patients won't know what is happening.(Technician_Government)*

Due to human resource crunch, the same technicians handle patients with and without infections such as Hepatitis and HIV, this coupled with their lack of adequate training puts patients at risk for infections. Other cost cutting practices reported were the use of lower quality water purifiers, and other equipment including dialysers and tubes. These practices led to patients getting infections and having other complications during dialysis. All centres used the dialyser for ten dialysis sessions for a patient and all three centres in Government reused the tubes as well. The technicians shared that if the machine parts were not cleaned with strict safety precautions, 'machine to patient infections' could happen. Technicians and duty doctors reported that they commonly saw infections such as Hepatitis C (HCV) and Hepatitis B (HBV) among patients. Staff from a few dialysis centres mentioned that they did not admit patients referred from certain centres due to the fear of transmission.

> *People with Kidney Disease are prone to get Hepatitis C and many hospitals are spreading it like anything. Some hospitals, I can name them, they are harbouring this and spreading. Patients coming from certain hospitals, we know that they will be positive, we know that their quality of treatment is poor.(Duty doctor_NGO)*

> *The water quality is very important; centres are supposed to have monthly water test to make sure the bacteria and toxic elements are controlled. But it costs about 4000-5000 rupees to do it, so most centres don't do it monthly.(Nephrologist_Private)*

DISCUSSION

This study throws light on the landscape of dialysis services offered in an urban setting in South India and poses a few important questions on the accessibility and quality of existing services. While it appears that the availability of haemodialysis services may not be a serious issue, economic access is a major challenge. Although dialysis services are predominantly offered by the private sector, the wide variability in charges for dialysis and support services renders them inaccessible for large groups of patients. Though the centres in the Government and NGO settings charge comparatively less per dialysis session, patients from poorer families still do not have sufficient resources to afford these. Also, such centres are too few in numbers to be able to cater to the rising demand for dialysis services. Our findings showed that due to financial constraints, patients are often forced to skip dialysis sessions. Similar findings were reported earlier by V Jha (2013)(32) and Karopady et al (2013)(33). Another study conducted by Gunjeet Kaur et al (2018) found the prevalence of Catastrophic Health Expenditure (CHE) to be as high as 51% among patients undergoing haemodialysis thrice a week(34).

In India, diabetes and hypertension are the key causative factors for CKD and these conditions make patients prone to complications during dialysis. Earlier studies have reported that hypotension, nausea and vomiting are commonly reported during dialysis, our study too showed similar findings(35). While infections, especially HCV and HBV are commonly reported in the CKD population due to frequent dialysis and blood transfusions, the number of centres catering to patients with these conditions are very limited. Patients with any comorbid conditions and other complications need to depend on higher centres with emergency facilities, which are too few in numbers, especially in public sector. The private hospitals can cater to only a subsection of ESRD patients, who can afford their services So, patients end up shuttling between centres in different settings depending on their illness status and paying capacity.

The study findings raise important questions regarding the overall quality of dialysis services across settings. The quality of the dialyser and water used for dialysis are important predictors for better patient outcomes(36), our study showed that the water treatment plants are available at varying costs and currently there are no mechanisms to ensure the water quality. Though the National guidelines and the guidelines issued by the Indian Society of Nephrologists recommend that nephrologists must be part of regular staff in the haemodialysis centres, the centres are managed solely by dialysis technicians and from our respondents' accounts, it appears that the quality of their training is variable. If technicians would be capable of identifying the early warning signs, many of the complications could be averted, including problems with fistula(37).

Though the benefits of peritoneal dialysis is well documented(38), our findings show that it is still not accessible to patients with CKD. Acknowledging this, the Government of India published a set of guidelines for states for starting peritoneal dialysis facilities as part of the Pradhan Mantri National Dialysis Programme(39). It provides the necessary guidance for the states to set up peritoneal dialysis centres and serve as a best practice document for providers of peritoneal dialysis and thus ensuring delivery of high quality, cost effective CAPD services. While it is a welcome move, states will have to implement it in an effective and timely manner.

CKD is known to be associated with various psychological issues such as depression, anxiety, and poor quality of life. A multi-centre study conducted in India found that depression was common among haemodialysis patients and long-term dialysis and poverty status had a significant relationship with depression(40). Another study conducted among CKD patients from Karnataka reported depression to be more common in patients on dialysis compared to other modalities of treatment(41). While supportive interventions have been found to be effective among patients with CKD(42), our findings indicate that the existing services do not cater to the psychosocial needs of the patients. Having the services of a trained counsellor or a social worker available in these centres would give the patients an opportunity to discusses their psychosocial problems, which could potentially help in reducing their emotional discomfort during the dialysis process and improve overall treatment outcome. Earlier studies have reported a positive effect of counselling on patients with CKD(43).

Limitations of the study

While the study provides a snapshot of the dialysis services provided in an urban setting in India, it is subject to certain limitations. The study took place in a selection of dialysis care facilities in an urban setting in India and the results might therefore not necessarily be generalizable to other settings. Due to the difficulty in obtaining necessary approvals from the authorities, patients undergoing dialysis services from the private sector could not be included in the study sample. The study respondents were undergoing dialysis for longer term, and we acknowledge that they represent a small subset of CKD patients and the finding apply to this subset of patients and not necessarily the entire spectrum of CKD.

Implications of the study and future directions

By including multiple stakeholders, our study offers a comprehensive perspective on CKD care in a lower middle-income urban setting. It also demonstrates the applicability of Bruce's Quality of Care Framework to ESRD care. The study highlights the need for more financial and personnel investments in ESRD care in India to ensure optimal care for the growing patient population. The study points towards the need for comprehensive management practices, including diet counselling and psychosocial support. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better access and quality of existing services. With the increasing burden of CKD in India, more in-depth studies are needed exploring patient experiences at different stages of their illness, which would help in designing appropriate interventions at each stage of CKD.

Contributorship statement

MAE conceptualised the study, in consultation with WVD and EW. MAE collected the data, conducted the first level of analysis, and prepared the first draft of the manuscript. WVD contributed to the study design, data analysis and writing the manuscript. EW contributed to data analysis and writing the manuscript. All three authors participated in data analysis discussions, revision of the manuscript and concurred on the final draft of the manuscript. All authors met the ICMJE criteria for authorship.

Competing interests

None to be declared

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article

Data sharing statement

Data can be made available on reasonable request

Acknowledgements

We thank Dr. Yashwanth Kumar KY, Assistant Professor, Department of Nephrology, Vydehi Institute Of Medical Sciences And Research Centre, Bangalore for his analytical inputs. We thank Prof Arima Mishra, Azim Premji University, Bangalore for her guidance and support. We acknowledge Dr. Thriveni S Beerenahalli for her help and support for the study.

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Dialysis Centre details	**Total number of centres**
Type of ownership	
Govt	3
Private (Individual)	8
Private (corporate)	6
NGO/trust	3
No of dialysis machines	
<5	2
6-10	11
11-20	5
>20	2
No of shifts per day	
Two	2
Three	12
Four	4
No of working days per week	
Six days	16
Seven days	4
Total number of Staff (including support staff)	
1-5	2
6-10	10
11-15	4
16-20	4
Other facilities available	
Pharmacy	12
Laboratory	9
Canteen	6
Services provided	
Haemodialysis	20
Peritoneal dialysis	0
Transplant	1
Diet counselling	3
Psychological counselling	0
Home visits	0

AVAILABILITY

Need to have sufficient quantity of functioning public health and health-care facilities, goods and services, and programmes.

- Do you collect data disaggregated by different and multiple stratifiers – such as infant/adolescent/older persons, rural/urban, people with disabilites, ethnic groups, men/women/transgender – on the availability of health facilites, goods, services and programmes for these populations?
- Are you looking at coverage gaps for populations that are not receiving a sufficient quanitity of facilies, goods, services, and programmes?
- Do you monitor the ratio of skilled health workers to the populations needs?

ACCESSIBILITY

Health facilities, goods, and services have to be accessible (physically accessible, affordable, and accessible information) to everyone within the jurisdiction of the State party without discrimination.

- Have you identified barriers to safe physical accessibility to facilites, goods, services, and programmes for different vulnerable or marginalised groups?
- Have you provided norms and standards that seek to overcome barriers to physical accessibility?
- Have you identified financial barriers to services for different vulnerable or marginalised groups?
- Do you monitor the extent to which health-related information is made available at country/district level for different vulnerable or marginalised groups including people with disabilities?
- Do your technical documents provide accurate and understandable information about your health area for all groups?

ACCEPTABILITY

The social and culteral distance between health systems and their users determine acceptability. All health facilities, goods, and services must be respectful of medical ethics and culterally appropriate, sensitive to gender and age. They also need to be designed to respect confidentiality and improve the health status of those concerned.

- Do you ensure that health facilities, goods, services and programmes are people-centred and cater for the specific needs of different populations?
- Are WHO programmes acceptable to diverse groups?
- Do you assure that goods, facilites, services and programmes are realised in accordance with international standards of medical ethics for:
  - confidentiality?
  - informed consent?

QUALITY

Health facilities, goods, and services must be scientifically and medically approved and of good quality.

- Have you established or ensured norms and standards of quality for:
  - health services?
  - health facilities?
  - health professionals?
  - essential medicines and equipment?
  - determinants of health?

Fundamental Elements of the Quality of Care: A Simple Framework

Judith Bruce

This article argues for attention to a neglected dimension of family planning services—their quality. A framework for assessing quality from the client's perspective is offered, consisting of six parts (choice of methods, information given to clients, technical competence, interpersonal relations, follow-up and continuity mechanisms, and the appropriate constellation of services). The literature is reviewed regarding evidence that improvements in these various dimensions of care result in gains at the individual level; an even scarcer body of literature is reviewed for evidence of gains at the level of program efficiency and impact. A concluding section discusses how to make practical use of the framework and distinguishes three vantage points from which to view quality: the structure of the program, the service-giving process itself, and the outcome of care, particularly with respect to individual knowledge, behavior, and satisfaction with services.

(STUDIES IN FAMILY PLANNING 1990; 21, 2: 61–91)

The last decade has seen considerable interest in identifying the critical features that make family planning (FP) services effective in meeting demand. Concurrently, the family planning field has rearticulated its commitment to individuals' and couples' right to make voluntary choices about the number and timing of the children they want, and select compatible means to achieve their goals. Yet, despite intensified concern with program performance and the ethics of family planning service provision, appraisals of family planning programs have generally neglected a central dimension—the quality of care rendered. The time has come to reverse this neglect. Improvements in the quality of services will result in a larger, more committed clientele of satisfied contraceptive users. Over the long term, this expanded base of well-served individuals will translate into higher contraceptive prevalence and, ultimately, reductions in fertility. Within private and commercial programs, where clients provide all or partial cost-recovery, the laws of the marketplace suggest that better services at the right price will attract more patrons. Within publicly supported programs, both clinic and community-based, it is likely that improvements in the quality of services will result in greater initial acceptance and more sustained use.

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Though the value of improved care will differ by setting, universal gains would be expected at the individual level in terms of personal well-being and the ability to regulate one's fertility. Speculating more broadly and in very simplified terms about the societal impacts of improved care, in parts of Asia, it is inadequacies in the array of services, and not simply limited contraceptive supply, that constrain expanded use of contraceptives and, in the long run, further reductions in fertility. In Latin America, contraceptive prevalence is generally high, with the stark exception of some indigenous populations and continuing but declining differentials between urban and rural prevalence. Concern exists in many Latin American and Caribbean countries that substantial misuse of self-employed methods occurs as well as overuse of sterilization, and excessive related unhealthful practices, such as delivery by caesarean section when unnecessary. Thus, in this region, the immediate impact of improving services and increasing effective use of temporary methods may be seen in improved client health rather than in the reduction of fertility, but over time, effects are expected in both. In sub-Saharan Africa, underlying health and cultural factors are complex and institutional capacity is limited. Though it may be tempting to make institutional improvements rapidly, services must be built up carefully, so as to engage the trust and patronage of African women and men in cultures where large numbers of children are still highly desired and uncertainty about and unfamiliarity with modern contraceptives may overpower an emerging and co-existent interest in birth spacing.

Beyond the global hypothesis that improvements in the quality of care are essential from human rights and demographic perspectives, it has been proposed that the largest potential reward for improving services exists where societal demand for child spacing and fertility regulation is low or unsteady—and, as a corollary, where maternal and child health (MCH) is poor. At both ends of the spectrum, whether demand is intense or very limited, improvements in the quality of services may only marginally increase contraceptive prevalence. Individual women who are virtually desperate to control their fertility will tolerate almost any type of care, including accepting methods that are unproven, incompatible with their health, and even life-threatening, such as unsafe abortion procedures. Nineteenth-century Europeans evolved social customs, engaged in specific sexual practices, and employed a high degree of abstinence to achieve fertility decline. On the other hand, for those who wish to have as many children as possible, with no or minimal spacing between pregnancies, an appealing family planning clinic or hospitable fieldworker may make no difference.

However, most societies and most people hold preferences between these extremes. Most do not want all the children they can physiologically produce, even if they hold high fertility goals. Most couples would prefer, if possible, to find an acceptable and safe way to enjoy an active sexual life while successfully avoiding constant pregnancy. In numerous different settings, the availability of services of reasonable quality will be of humane value to the prospective clients and, over time, should assist the achievement of national demographic goals.

Defining Quality

Very few systematic studies are available to guide us in defining and measuring the quality of services, but we do not begin at zero. The extraordinary analysis and documentation of the family planning programs operated by the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B) in Matlab Thana, and its efforts to transfer this knowledge to the regular government program in what are known as the "extension areas," provide an unparalleled picture of the features of a supply system, its management structure, workers' roles, and clients' responses. The recent assessment of family planning effectiveness by the National Academy of Sciences (Lapham and Simmons, 1987) was a masterful synthesis of knowledge about programs and gave a good deal of weight in its analysis to client/provider transactions. Lapham and Mauldin's (1985) review of program effort in 100 countries, though relying upon informants rather than clients, sought to go beyond official enunciations about availability to describe services in more realistic terms.

Analyses of the availability of services (Hermalin and Entwisle, 1985) and the monetary costs of services to clients have necessarily involved considerations of quality. Indeed, these three issues—quality of services, their cost, and availability—are difficult to consider discretely: a choice of methods is not possible without sufficient supply points. The interpersonal dimensions of care are strongly influenced by the quantity of care—the amount and nature of contact between the client and the provider system. The continuity of care provided is similarly influenced by access to supply points and/or staff. Health planners and individuals alike link costs and quality in their decision-making. Health planners' determinations about which improvements in quality to pursue are founded to some extent on considerations of cost. At the individual level, the client's willingness to pay for services may vary with their perceived quality.

Though it is acknowledged that these topics—availability, cost, and quality—are related and indistinctly bounded, the purpose of this article is to draw a box around the phrase "quality of care" and identify its fundamental elements in family planning and related reproductive health programs.

Confusion about the meaning of the word "quality" itself may have inhibited more rapid progress in this area. Quality, by its connotation, implies an intimidating, possibly costly standard. It is not a standard at all, though; rather, it is a property that all programs have (Donabedian, 1980, as cited in Simmons, 1987).[1] Only a judgment can determine whether quality is good or bad, satisfactory or unsatisfactory. The word and its imputed meaning have emerged in *contradictory contexts*: early family planning literature discussed quality largely with regard to clinical operations; this approach neglected the interpersonal dimensions of care and suggested to some that high quality meant technically sophisticated, expensive equipment. Quality has sometimes been counted as synonymous with the availability and/or accessibility of contraceptives. Both quality of care and availability of services are vital determinants of contraceptive use, but studies of availability rarely provide descriptive material on the unit of service clients receive. Quality has also been defined in terms of potential demographic impact; a recent evaluation of a major Asian family planning program included the proportion of women using long-term methods as a measure of quality (Bair et al., 1987).

These conflicting approaches to the definition of quality and the suggestion that it is unmeasurable may have discouraged managers from incorporating quality of care indicators in their management information system (MIS) and evaluation protocols. Managers have been accustomed to measuring quantity of services provided, by type. Donors' evaluation frameworks, the daily mechanism of management, bureaucracies and their own internal reward systems, and the national government's desire to meet targets—whether counted in demographic terms or numbers of services rendered—have all led to a strong bias to evaluate performance based on volume of activities, sometimes calculated from the base (the individual worker) up to program, subnational, and national levels. The quantitative bias is a powerful force with which to contend.

The sources of information, of tools, and of intellectual sustenance in developing measures of quality will not be found in the scientific literature alone. This literature assists us to some extent, but learning the family planning field's experience, much of it transmitted orally or noted in site visit reports, is also vital. Managers, technical specialists, and workers alike have their own folk knowledge about what constitutes good or adequate quality. This knowledge needs to be revived, revalued, and structured. One is often struck by the dichotomous nature of the population field's self-expression. Quantitatively oriented research and evaluation studies give a dry, satisfyingly organized, if partial picture of the supply of services. In contrast, accounts of personal experiences and trip reports have quite another flavor. Some anecdotes convey a world of meaning about the quality of the service received; for instance, when one woman who had purchased her first pills from a pharmacist asked how to take them, she was told, "The way you take all other pills."[2] A family planning evaluator who recently returned from the field described seeing several women lined up on examining tables, with their legs open, as a physician moved among them inserting IUDs in a space less like a medical facility than a "cage." Most professionals in our field are troubled by this insensitivity and incompetence, but no ready means exist for integrating this discomfort into an evaluation framework.

If quality of services is going to rank alongside quantity of services as an indicator of program performance, the "classical" clinical dimensions of quality of care and the subjective interpersonal aspects must be brought together in a simple and generally agreed-upon framework. Donabedian (1980, 1988) has provided a generic foundation for assessing the quality of health services. This present paper, informed by Donabedian's technical/interpersonal model of care, seeks to specify the quality of family planning and related reproductive health care services. The selection of the six elements and the emphasis placed on them reflects not only logic, but the author's view of the field's experience and the tension created when family planning services are caught between two potentially conflicting mandates: promoting the achievement of demographic objectives and meeting individual health and welfare needs. The framework seeks to respond to the common sense and commitment to human welfare that motivated the work in this field in its early stages.

Quality of Care Framework

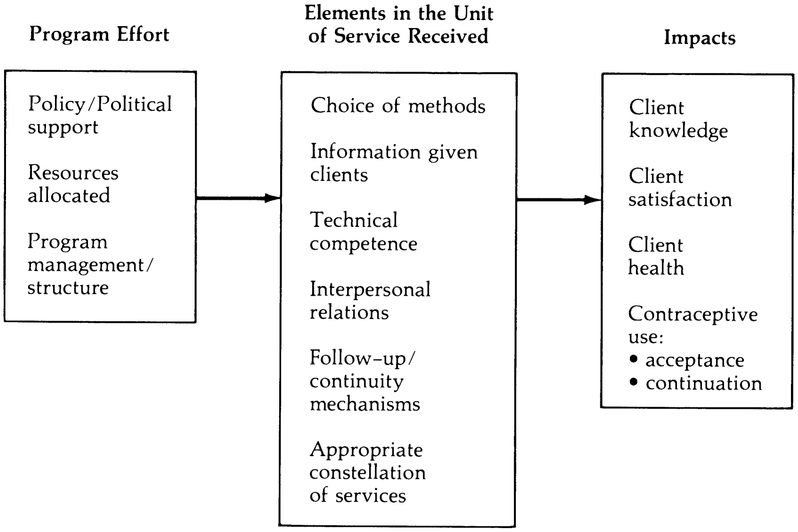
The salient elements of family planning programs that together constitute quality are: choice of methods, information given to users, technical competence, interpersonal relations, follow-up or continuity mechanisms, and appropriate constellation of services. These elements reflect *six aspects of services that clients experience as critical*. This framework is meant to provide an ordered point of departure from which to develop a description of the service unit and define its quality. Though we are concerned with the experience of those who have not successfully connected to services—particularly when their nonuse is attributable to poor availability or negative reports of service—for the moment, our *attention is centered on the experience of those who have gained access to services.* The client usually does not see the apparatus behind her experience, all the vital work required to provide services. Thus, the policies, resource allocation decisions, and management tasks that precede the delivery of services are not directly experienced, but their outcome, the service-giving, is. Figure 1 is a graphic display of the framework and the hypothesized relationships between program effort, quality of the service experience, and its impacts.

The Six Elements

Choice of methods refers both to the number of contraceptive methods offered on a reliable basis and their intrinsic variability. Which methods are offered to serve significant subgroups as defined by age, gender, contraceptive intention, lactation status, health profile, and—where cost of method is a factor—income groups? To what degree will these methods meet current or emerging need (for example, adolescents)? Are there satisfactory choices for those men and women who wish to space, those who wish to limit, those who cannot tolerate hormonal contraceptives, and so forth?

Information given to clients refers to the information

Figure 1 The quality of the service experience—its origins and impacts



imparted during service contact that enables clients to choose and employ contraception with satisfaction and technical competence. It includes: information about the range of methods available, their scientifically documented contraindications, advantages, and disadvantages; screening out unsafe choices for the specific client and providing details on how to use the method *selected*, its possible impacts on sexual practice, and its potential side effects; and finally, an often neglected element, explicit information about what clients can expect from service providers regarding sustained advice, support, supply, and referral to other methods and related services, if needed.

Technical competence involves, principally, factors such as the competence of the clinical technique of providers, the observance of protocols, and meticulous asepsis required to provide clinical methods such as IUDs, implants, and sterilization.

Interpersonal relations are the personal dimensions of service. Relations between providers and clients are strongly influenced by a program's mission and ideology, management style, resource allocation (for example, patient flow in clinical settings), the ratio of workers to clients, and supervisory structure.

Mechanisms to encourage continuity can involve well-informed users managing continuity on their own or formal mechanisms within the program. They can rely upon community media, or on specific follow-up mechanisms, such as forward appointments, or home visits by workers.

Appropriate constellation of services refers to situating family planning services so that they are convenient and acceptable to clients, responding to their natural health concepts, and meeting pressing pre-existing health needs. Services can be appropriately delivered through a vertical infrastructure, or in the context of MCH initiatives, postpartum services, comprehensive reproductive health services, employee health programs, or others.

The six elements of this framework are not utterly discrete. Their quality is interrelated, often determined by common background factors and program policies, operations management styles, and resource limits. Yet, these elements are separable enough that program staff, evaluators, or especially alert clients could develop distinct opinions about each of them. They could also represent points of intervention: methods can be added to the mix, information can be expanded and updated, more appropriate medical protocols can be developed, workers' counseling skills can be improved, follow-up mechanisms can be put in place, and selected services can be added to a program. However, because even incremental change is often difficult to achieve and involves costs in time and money, in the next section research findings and program experience are related that may encourage reviews of service quality. Further, as this framework has practical applications without necessarily heroic efforts, the ways in which health planners, managers, and researchers might use the framework are discussed briefly. A much expanded discussion of its applications, including indicators that could be employed for clinically centered services, is provided by Kumar et al. (1989). In the sections that follow, the impact of each of the six elements in the framework is discussed. In the final section, practical applications of the framework are described.

Choice of Methods

Rationales and Meaning of Choice

It is by now a central principle of family planning programs that a choice of methods should be provided. Providing a choice does not necessarily mean that every program must provide all methods, but the overall program effort on a geographic basis should be sufficient so that prospective users have reasonable if not utterly equal access to a variety of methods.

Over the years, a variety of rationales have been offered to support the proposition that providing a choice of methods is important. Though obvious, it bears repeating that individuals and couples pass through different stages in their reproductive life cycle, and their needs and values change. They may move from wishing to delay childbearing, to space pregnancies, and finally, to terminate childbearing. Many marriages and partnerships dissolve and new ones form, migration leads to spousal separation, and finally, the death of the spouse in midlife is not uncommon. The clinically documented and perceived health risk of specific methods to specific women is a second reason arguing for choice. Despite careful screening for medical contraindications, the process of taking personal and family medical histories from clients does not tell them very much about the possibility of the appearance of unpleasant side effects nor does it necessarily indicate which of these they will be able to manage. A majority of discontinuation of methods in the first year is attributable to side effects. The most comprehensive study (Kreager, 1977) found that in the range of studies of first-year continuation rates, 4–34 percent of IUD acceptors had the devices removed for medical reasons or due to untolerated side effects, and 8–50 percent of pill acceptors discontinued use for the same reasons.

Much about contraceptives has changed in the decade intervening since Kreager's review. For example, the hormonal contraceptives most widely distributed in 1989 have a far lower dosage than their 1970 equivalents, and some contain no estrogen. These biomedical advances are positive from the point of view of women's cardiovascular systems, and have reduced the possibilities of negative health consequences, but they have *not* eliminated side effects. Indeed, some of the lower-dose hormonal methods carry with them a greater probability of extended periods, unpredictable breakthrough bleeding, and other effects of consequence to users. The Dalkon Shield, a dangerous intrauterine device, has been removed from the market, and the newer configurations are long-lasting, easier to insert, and better tolerated by low-parity women. Nonetheless, as with the improved range of hormonal methods (in oral, injectable, and implant formats), users' problems with IUDs are often not predicted through screening but only revealed through use. The increased knowledge about the infection-promoting or inhibiting effects of different contraceptives may intensify the health factor in clients' decisions. Also, women desiring to protect their fertility and health while practicing contraception for possibly decades (from menarche to first birth) may have an increased interest in temporary methods with no known infertility effects.

Thus, switching among methods is common, particularly among first-time and adequately informed contraceptive users. The ability of individuals to switch methods is key to their satisfaction and their ability to practice contraception over a long term. Indeed, observed patterns of contraceptive use make it clear that in industrialized and developing countries alike, first-use segments with temporary methods of contraception are typically under two years. Mauldin's (1978) review of contraceptive continuation rates estimated that (based on data from 33 countries), of 100 women who have an IUD inserted, 34 have it removed before one year, and an additional 10 have it removed in the second year. Of 100 women who have accepted and used oral contraceptives, 55 abandon them before year one, and another 16 discontinue use during the second year. A recent study of contraceptive use among US women indicated that the median use segments of temporary methods was about two years (Grady et al., 1987).

Comparative data from developing countries are more difficult to find. Most studies have been so oriented to looking at the experience of individual (usually clinical) methods that they generally deal only with first-method discontinuation and therefore give no sense of the sequential use of contraceptives by individual users. In developing country settings, there may be fewer methods available to permit switching and fewer cohorts of women who pass through reproductive ages when a meaningful choice of methods was available. If one compares data from the contraceptive prevalence World Fertility Surveys on ever-use and current use, it is clear that many current users are not using the method first selected. Field studies of contraceptive use patterns among specific populations, however, usually verify the assumption that much switching goes on, and some studies have found that switching among methods correlates with long-term use. Data from a household distribution scheme in Bangladesh indicate that two-thirds of those women still practicing contraception 18 months after the initial distribution of methods had switched methods (Bhatia et al., 1980). Philippines data drawn from the national acceptors survey show that 34 percent of the women who were still using contraceptives at the end of 24 months had switched methods at least once (Laing and Alcantara, 1980). In the course of a ten-month study of 200 family planning clients drawn from seven clinics in Botswana, 10 percent switched methods at least once (Stephens, 1978).

There also may be societies where couples' selections are more resistant to change once established. For example, DaVanzo et al. (1987) presented data from Malaysia (1961–75) on contraceptive switching among three different ethnic groups. In general they found an unusual inertia; most women stayed with the same method not simply over time, but from pregnancy to pregnancy. However, they also observed less stability in choice among those who had adopted modern methods. Calculating continuation rates with specific methods between pregnancies they found continuation rates of 73 percent for rhythm, abstinence, and withdrawal; 55 percent for barrier methods; and just over 50 percent for pill use.

Having a choice of methods is both a practical and philosophical commitment to respond to the user's needs. Practically, providers must carefully plan how to provide alternative technologies to clients. Philosophically, the availability of multiple methods reaffirms the program's goal of service to the individual's need for effective contraception, not the promotion of a given method. This orientation to meeting individual requirements as a prerequisite to providing choice in a meaningful fashion bears emphasis. In a now famous set of experiments, a contraceptive program in Bangladesh promoting oral contraceptives with condoms as a second choice was followed by a program that explicitly defined its focus as "client-oriented." This latter program operated in the same area with better-trained workers and seven contraceptive modalities available, resulting in dramatic contrasts in their results, both short-term, as measured through acceptance and continuation, and long-term, as measured through fertility decline (Bhatia et al., 1980; Phillips et al., 1982).

A recent review of the ongoing experience in Matlab and the extension areas with the introduction of new contraceptive methods suggests another vital dimension of providing choice that must be understood. *Real choice is not feasible without an adequately developed delivery system.* Phillips (1988) reviewed the impact of the introduction of depot-medroxy-progesterone acetate (DMPA), an injectable contraceptive. He concluded that, whereas DMPA met the needs of a large clientele and led to a consistent and large layer of use in the Matlab experimental areas, its introduction outside in the extension areas could not be deemed a success. This was not because clients did not welcome its addition, but because the service personnel, visiting pattern, and general intensity of resources were insufficient to deliver DMPA consistently and up to standard. Similarly, the new contraceptive implants, such as NORPLANT®,[3] will become a choice in reality only in contexts where technical competence is assured.

The offering of choice must also recognize the undesirable, but frequent, occurrence of inconsistent supplies. If multiple methods are offered, the likelihood increases that at least one method will be available. Even better, some analysts say, is a program effort in which a variety of methods (both supply and clinical) are available through a variety of sources (Foreit et al., 1978).

Choice and Program Performance

With regard to impact, the role that choice plays in increasing the demographic effectiveness of programs is now well documented. A clear, consistent, and positive relationship exists between the availability of a range of contraceptive methods and contraceptive prevalence rates (Freedman and Berelson, 1976; Mauldin, 1979; Pebley and Brackett, 1982; Potter, 1971; Lapham and Mauldin, 1985). The most recent assessment, and a powerful one, is by Jain (1989), who reviewed the evidence and modeled the relationship between increasing the number of methods available and the demographic impact of programs. Jain lists four central findings from the existing data that indicate the positive demographic impact of method choice. His analysis indicates that:

1. The addition of a method results in a net addition to contraceptive prevalence.
2. One-method family planning programs are inadequate to meet individual fertility goals.
3. Availability of multiple methods improves continuation of use.
4. Contraceptive prevalence depends upon the number of methods available at multiple service points in a country.

Reanalyzing data collected by Lapham and Mauldin (1985), Jain found that a little less than two methods were effectively available per country, and the countries with more methods available had markedly higher contraceptive prevalence. He modeled these relationships and concluded that, "the widespread addition of one method . . . to the choice of methods available in a country would be associated with an increase of about 12 percentage points in the practice of contraception" (Jain, 1989: 11).

Relatively very little research has been done to learn explicitly from users how their perception of a choice of methods is reflected in their sense of satisfaction with the program and their contraceptive use. However, a great deal of indirect evidence demonstrates how a lack of choice affects clients' behavior. In a recent study of oral contraceptive, IUD, and condom acceptors in five Indonesian family planning clinics, clients were asked 18 months after their initial contact whether they had received the methods they requested, whether they were still using contraceptives, and, if not, when they had discontinued. Of those who reported they had not received the method they wanted, 85 percent had discontinued within a year. The comparable rate among those who received the method requested was 25 percent. Whether a client's choice of method was "granted" or "denied" turned out to be more powerful than all other independent variables in explaining the tendency to continue or discontinue use. Regardless of method, women who did not receive their original request had lower continuation rates (Pariani et al., 1987).

The consequences of programs not responding to individual client's choice on a first or subsequent contact is discussed in several studies in different parts of the world. Indirectly, the World Health Organization (WHO) free choice studies (WHO, 1980) indicated a fair amount of non-free choice (that is, all options were not indicated, and/or access was limited), considering that as many as 40 percent of women in different clinic sites would switch methods when they were provided with fuller information and more equal access. Clients otherwise committed to practicing contraception may be discouraged if they are not given usable information or the desired method is not easily available. For example, information from Niger (Maidouka, 1986) indicated that women who did not receive a method on the first visit did not return. A study of three clinics providing family planning services in Dakar, Senegal (Nichols et al., 1985) not only found a poor balance among the three methods provided but also found that nearly one-fifth of first-time visitors received no method at all. A conclusion of the study was: "It is evident that contraceptive dispensation at the three clinics is not tailored to the particular needs and reproductive intentions of the client populations, but rather to method availability and orientation of the respective clinic personnel" (1985: 274–275).

The effective denial of a chosen method can also result from "punitive quality" (discussed later), where unnecessarily high or irrelevant medical standards are set for the provision of methods. Bailey and Keller (1982), studying post-family-planning experience in St. Kitts, Nevis, and St. Vincent, found that 12 percent of women in their sample (who used methods other than the pill or the IUD) stopped using contraceptives because they preferred another method. This fact, combined with the low return rate to the clinic for scheduled appointments (85 percent of acceptors failed to keep all their scheduled appointments), makes clear the *importance of discussing the availability of a choice of methods on first contact*. Termination with a given method need not translate into "program termination" if clients are made aware at the outset of the range of options available and the readiness of the service to provide them.

Choice from the Client's Perspective

A number of analysts have creatively explored the factors influencing the individual's choice process. Bulatao (1985), for example, sees four dimensions to the individual's process: (1) balancing contraceptive goals with (2) their personal competence, (3) their evaluation of the contraceptive, and (4) contraceptive access (virtually solely the responsibility of the provider).

Hollerbach (1982) discusses the acceptability of the properties of methods (not programs). Users' assessments of contraceptives have many bases, the most important of which appear to be their effectiveness and their safety. Convenience and method of administration (that is, by injection, orally, and so on) are also important. The point here is that providers should understand the need for an intrinsic variety in the methods offered. For instance, a choice of three hormonal methods, although administered in different ways (for example, the pill, DMPA, and implants) can have similar side effects and therefore pose the same acceptability problems to users.

What is Informed Choice?

Finally, what comprises informed choice and how can it be measured? Do we need to develop culture-specific standards of "full and balanced information"? The information given to users must be practical and manageable. Thus, it is likely that trade-offs will occur between different elements of full and balanced information.[4]

Is it realistic to expect that clients want and require a full-scale lecture or will retain equally all information presented? Is it sufficient to go into detail with the method they select at the moment and emphasize the availability of other methods if their first choice becomes unacceptable after use? This is an important question for empirical investigation because many managers cite resource limits as a principal reason for neglecting superior information dissemination or counseling. Perhaps family planning programs should seek to impart to the client two central concepts—*choice and change,* with an emphasis on the following points:

- —There is a choice of methods, and all have distinctive risks and benefits.
- —Choices are provisional, and decisions are reversible (provided the method is); acceptance of a method is thus a trial.
- —Clients' needs and preferences often change over time.
- —Discontinuation is no failure on the part of the user or provider.
- —The present provider or others, upon referral, have the information and supplies to assist clients in maintaining their current choice or switching methods.

Perhaps these ideas, successfully delivered along with more in-depth information about the method selected, will sufficiently serve the client's interest in choice and support effective use.

Conclusion

In sum, choice is not only the first, but the fundamental element of providing quality in services. The evidence is overwhelming that a range of methods, competently provided, will attract more acceptors and provide for the switching among methods that is the foundation of satisfied and sustained use. The managerial task of providing choice is a complex one. Because "choice" of temporary methods is an ongoing affirmation and not the result of a one-time contact between client and a single provider, individual programs in the larger structure must carefully plan for expected fluctuations in individuals' needs. The ill-prepared introduction of a technology does not constitute the expansion of choice; choice implies the provision of methods up to some standard of technical and interpersonal care. Clients' own perception of whether they have received a choice is a subject for further study, but what is known of contraceptive use dynamics suggests that a long-term view is necessary and the provider's role should not be seen narrowly as the purveyor of technologies, but as a source of continuing support for individuals as their requirements change.

Information Given to Clients

Evolution in the Meaning of Information-Giving

The identification of the three aspects of information-giving (noted earlier) springs from a concept of technology that integrates the contraceptive device, procedure, or drug with the information given to the user about it.

The first aspect noted, the informational component of choice, insists that clients appreciate that a variety of methods are available, each with distinctive features. (This sharing of information is quite separate from promotion.)

The second aspect of giving information seeks to enable the user to employ the method effectively and to appreciate the method's potential to create physical changes, healthful or unhealthful feelings, and the impact of these experiences on daily activities and the most intimate aspects of partnerships. If clients do not retain usable and correct information, they cannot comply with the requirements of self-employed methods (condoms, spermicides, diaphragms, and oral contraceptives). If clinical methods, like IUDs and implants, are not explained sufficiently and their potential side effects appreciated, users are much more likely to discontinue use (Berelson, 1966). Unanticipated or unmanaged side effects lead to disappointed clients and result in discontinuation of contraceptive use, as Kreager (1977) persuasively documents.

This second aspect of giving information is closest to counseling in the sense that the provider and client seek a match from among the safe methods for a specific client. The provider should make clear that the use of a contraceptive technology has ramifications beyond simply regulating fertility. The individual is selecting a "therapy" that must mesh with his or her intimate sexual and social needs (see the more expanded discussion in Bruce, 1987). For example, many modern methods cause unpredictable bleeding. The impact of sporadic bleeding on religious custom, work habits, and sexual relations for many women is a vital consideration.

If this text had been written 15 or perhaps even 10 years ago, information-giving would have been called simply "screening." In the past, it was screening that received the most attention as a "quality" issue. In the late 1960s, the primary criteria of quality were the provider's professional standing and competence, as well as the care with which the client's health status and methods profile were matched. Questions were raised as to whether paramedical personnel would be as competent as medical doctors in identifying and preparing appropriate candidates for the use of modern methods, especially oral contraceptives (Rosenfield and Limcharoen, 1972). (It was found, and has been confirmed in diverse sites, that well-trained paramedical staff are equally able as, if not better than, physicians to communicate with clients about their health needs, take health histories, and identify clients with relative or absolute contraindications.)

In the 1980s and 1990s, the quality issues must go beyond concern about the ability of different levels of personnel to screen clients and move on to embrace a broader and possibly more difficult question: How far can screening go in ensuring informed choice and acceptability? Regarding informed choice, screening is an essential element insofar as it seeks to exclude from the pool of acceptors women or men who might experience dangerous health conditions as a result of specific contraceptive choices. For example, it is vital that women who are heavy smokers be advised against using oral contraceptives. As regards acceptability, however, and some adverse health effects, screening provides very little guidance. Paradoxically, the advances and the formulations of many modern methods that have rendered them clinically safer than they were originally have reduced the potential contribution that screening makes to satisfactory contraceptive use. Many modern method side effects that cause concern among users are often not medically dangerous, but rather are physical experiences that the user or the user's partner may not like. The present state of knowledge and practice, however, does not permit us to know with high levels of accuracy who will have breakthrough bleeding, headaches, or nausea with certain hormonal methods. Even where such events might be predicted, screening does not identify an individual's ability to tolerate them.

In sum, an individual's potential to experience and tolerate side effects is difficult to reliably anticipate and, thus, their occurrence is not measurably reduced through screening. The necessarily delayed knowledge on the part of the user, regarding problems she or he might have, underscores the importance of the third aspect of information giving: developing an appropriate expectation on the part of the client as to the service provider's forward role in giving advice, supplying methods, and referring other methods or service sites.

The clients' willingness to return to a service provider will relate in part to their comfort with the client/provider interchange, but recontact will also be promoted by specific content in the initial interview, such as the existence of a reappointment, the explicitness on the part of the information-giver that the client may have problems with the method selected, questions that need answering, or needs for reassurance. When delivering a method whose effectiveness is time-limited (such as medicated IUDs, implants, and injectable contraceptives) or that carries a risk of complications, the information that assures recontact is as essential to the client as is a description of the method and how to use it.

Clients' Information Levels and Program Performance

Little is known about the direct impact of information given to users on contraceptive prevalence. The effectiveness of mass media in altering contraceptive knowledge and behavior has been the subject of sometimes inconclusive research, much of which was conducted in the 1960s and 1970s. Recently, Lapham and Mauldin (1985) included extra-clinical information and education activities of an overall program as an indicator of program effort, but provided no assessments of the "strength" of the information given to clients one-to-one. In the 1990s mass media will likely be of growing importance, because the number of low-income families in Third World countries who have radio access has vastly increased since the first communication impact studies were conducted (Population Reports, 1986). There is great potential good to be yielded from broadcast information (as distinct from promotion) about contraception. Effective broadcasting could create an environment of accurate knowledge of a range of methods among potential family planning clients and encourage more effective self-care. However, regardless of its media environment, each program has to evaluate the adequacy of the information it directly imparts to clients. While no impact analyses are available of this dimension of service-provision, solid data exist supporting the contribution that sound and well-presented information makes to users' knowledge base and effective contraceptive behavior.

Evidence of the importance of providing written as well as oral information comes from small-scale studies, many of them conducted by the Program for Appropriate Technology in Health (PATH). These data (Haffey et al., 1984) indicate that most people remember messages better if the spoken word is reinforced by written or pictorial messages. Such visual materials support program staff in remembering and systematizing all they are to transmit, and they help the clients as well. For example, booklets for oral contraceptive users were introduced in a program in Bangladesh. One month after receiving this booklet, which described how to use oral contraceptives, 83 percent of the booklet recipients were still able to state when to start taking the pill, as opposed to only 16 percent of the control group, who received only verbal instructions. In Sierra Leone, PATH experimented with the value placed on written material. Seventy-eight percent of the women who received a booklet on the pill not only kept the booklet, but also used it to tell friends and relatives how and where to get more information.

The role of information in assuring clients and in contributing to contraceptive prevalence can be seen in a study by Keller (1973) of five Mexican family planning clinics. This study classified as "users" those patients who kept their last appointments within two months of their return date. "Deserters" were clients who were over two months late for their last appointment. This definition seems to be highly realistic, as it was found that 90 percent of women who did not return within two months also did not return within two years. The research demonstrated a strong relationship between the receipt of accurate information about methods, including anticipated side effects, and the propensity of clients to continue with methods and to resist negative, ill-founded rumors (Keller, 1973).

Another study, conducted in Bogotá (Measham, 1976), compared women who bought oral contraceptives from pharmacists or non-family planning outlets (called self-subscribers) with those who received pills from physicians (private or family planning units). Two points are interesting from the perspective of quality of information. Twice as many self-subscribers reported side effects than those obtaining orals from physicians. Lacking a reference point for medical review, almost two-thirds of the self-subscribers did not seek any help. This translated into slightly greater discontinuation rates among self-subscribers than among the users of traditional medical services. As the family planning program of India has increased the availability of spacing methods, the family planning association has intensified its concern with how to assure quality in the use of the IUD, a method with an uneven career in India. A recent study (Prabhavathi and Shenshadri, 1987) determined that incomplete information and poor follow-up led to measurably lower contraceptive continuation rates: ". . . Twelve-month life-table continuation rates are .6256 among those with incomplete information, compared to .7069 among those who were given more comprehensive information on side effects and other family planning methods prior to acceptance" (1987: 15).

Clients' and Providers' Misinformation

Since 1976 the number of self-subscribers of contraceptives has dramatically increased. Pharmacists worldwide play an expanded role in contraceptive distribution as women seek fertility regulation independent of the formal medical system and as the number of women who initially obtained contraceptives through clinical sources preferentially seek resupply from nonclinical outlets. A measure of this comes from Brazil, where the Brazil 1986 Demographic and Health Survey showed that about 93 percent of women there who use the pill got their supplies from pharmacists (IRD/Westinghouse, 1988). This and other surveys are confirming the increased access of women all over the world to commercially sold contraceptive supplies.

The public's expanded knowledge of contraceptives has not been paralleled by their knowledge of safe and effective use. Research from many countries has indicated extensive misunderstanding and misuse of methods with potentially serious consequences to clients and overall program effort. The task at hand is not simply to educate providers and potential clients better, but to cope with well-developed fears of specific contraceptives. Recent studies provide examples of how defective popular information about oral contraceptives is. In a study of eight developing countries, 50–70 percent of the women thought the pill posed considerable health risks (Grubb, 1987). Of special interest, and a measure of the consequence of misinformation, "26 to 60 percent of users (except in the Mexican sample) had stopped taking the pill because they worried about its safety and for each sample, a lower or similar percentage of never-users said they had not taken the pill for this reason" (Grubb, 1987: 318–319).

DeClerque et al. (1986) investigated rumor, misinformation, and oral contraceptive use in Egypt. They looked for, and found, a great range of concerns about the pill, including those linked to local cultural concepts. Their conclusion makes an important point regarding the reality of women's perceptions. High-dose pills (which continue to be distributed in parts of Egypt) and the poor health of women may indeed cause fatigue, which is verbalized as "weakness," among these women.

A study of family planning practice among nearly 1,800 women in a low-income area in Rio de Janeiro found that of the entire sample of family planning users, 34 percent were using pills; 23 percent of these were using pills incorrectly. Only 43 percent of the oral contraceptive users had received any medical orientation before purchasing the pills (Costa et al., 1987). The extent of self-prescription for this population resulted in serious misuse: 43 percent were smokers, the majority of whom smoked over ten cigarettes a day. Five percent of pill users were both heavy smokers and over 45 years of age.

A study conducted in Magdalena, Colombia, where most oral contraceptives are distributed by rural health promoters, provides evidence of a relationship between client's compliance and continuation with oral contraceptives and characteristics of the distribution system (Potter et al., 1987). Five hundred and seventy-two female users of oral contraceptives were interviewed three times. Twenty percent of them had already discontinued by the first or second interview (within two to six months after acceptance). Fifty-eight percent of the 340 current users used the oral contraceptives incorrectly within a two-week period. The promoters themselves were confused about key aspects of pill use, such as when to start the next pill packet. Only 54 percent knew the correct new time for a 21-day cycle and 44 percent for a 28-day cycle. Only 25 percent of the promoters had any information about how to treat nausea in the first three months.

Astonishingly poor provider information levels have also been documented in Guatemala (Townsend, 1987), Colombia (Townsend and Ojeda, 1985), and on baseline surveys conducted of pharmacists in different parts of Latin America (Rizo, 1979). Assuming providers' knowledge of methods can be improved—and experiments with community-based distributors (CBDs) and pharmacists have indicated that it can be—in what way does this increased knowledge translate into more contraceptive use? The limited data available provide no clear guidance. Research in Colombia (Townsend and Ojeda, 1985; Vernon and Ojeda, 1988) has not found a consistent relationship between better-informed providers and more sales of contraceptives. In these studies, however, though distributors' knowledge levels were increased, they were still very low, perhaps not reaching the threshold where effects can be seen. Further, the output measure that was selected—sales volume—can be misleading because some distributors sell wholesale while others sell only retail, and long-term distributors generally have a larger client load than do newer ones. These findings are not supplemented by information about clients' compliance with use regimes, clients' continuing use over a period of time, or client satisfaction.

Conclusion

These collective observations suggest that a revolution in information about contraception is needed. The pool of men and women who know the names of modern contraceptives and have used them appears to be ever-increasing. Yet, there persists in the general public and even among current clients poor knowledge of the proper use, risks, and benefits of contraceptives. Lack of information is a reason for discontinuing method use, and belief in rumors may be a deterrent to use altogether. Contact between client and provider after the first encounter is irregular. This is true because too little attention has been given to establishing continuity or follow-up mechanisms and because of clients' characteristics—their geographic mobility, the desire for privacy, and so forth—which may tend to make them move among supply points. Finally, despite some concerted efforts, gravely inadequate levels of information are found among primary providers in clinic, commercial, and community-centered systems alike.

Technical Competence

Technical competence is the element in the framework least easily judged by clients. Typically, clients evaluate providers more on the amount of time they spend with them and their caring attitude (Gay, 1980, 1988; Sung, 1977; Lynn et al., 1985) than their technical skills. Clients often do notice obviously dirty conditions, but they tend more to remember and report on discomfort and to differentiate between discomfort they did and did not expect. Even though lacking the ability to fully evaluate clinical competence, clients bear the consequences of poor technique in the form of unnecessary pain, infection, other serious side effects, and in some circumstances, death.

Clinical incompetence is rarely specifically reported but is often part of a wider pattern of poor program performance. Of all the literature reviewed for this paper, documented evidence of poor clinical procedure and its consequences was the most difficult to locate. (An exception to this is the detailed study of sterilization deaths in Bangladesh discussed below.) Assessments of unsanitary physical circumstances, poor observance of asepsis, gross errors in technique, or the application of inappropriate medical standards are made in writing in internal reports and other fugitive literature. However, citable material is rare. One reason for this is undoubtedly political; an evaluator who uncovers serious problems may not wish to publicize them because this may hamper collaboration with the provider in the urgent problem of improving care. It is also plausible, though, that the special status held by clinical practitioners, particularly M.D.s, may be another reason. As references in the rest of this article attest, candid evaluations can be found about the knowledge and abilities of CBDs, pharmacists, and even managers. Clinicians, however, seem to be largely protected from objective public reporting.

Technical Competence, Technology Transfer, and Program Performance

Despite the lack of documentation, strong indirect evidence of the impact of insufficiently trained providers can be detected in accounts of program or nationwide experience with specific contraceptive methods. Providers who are uncertain of their skills are sometimes reluctant to use them or, worse, apply them badly. Neither approach contributes to clients' health or increased contraceptive prevalence. Indeed, such providers' performance generates negative rumors about programs and methods. For example, the failure to successfully introduce the IUD in India was attributed to an insufficient program effort to train, field, and supervise staff:

> The IUD was an inexpensive, reversible, and effective method; it could be inserted by trained auxiliaries; it appeared to fit every requirement and was enthusiastically introduced. . . . But success and optimism were short-lived as inadequacies in pre-insertion checks, poor follow-up, medical complications, and grossly exaggerated rumors about complications led to high discontinuation rates and a seven-year slump in annual insertions [down from over 900,000 in 1966–67 to 370,000 in 1973–74] . . . The program had quite simply been rushed through without organizational preparation to cope with the known side effects, which turned out to be more widespread among the population of malnourished, anemic women who were not forewarned about what to expect (Soni, 1983: 41).

In Bangladesh, rumors about sterilization deaths led to an international effort to evaluate the sterilization program and document the death rate for tubectomies as well as vasectomies. The relatively high rates in 1979 (estimated at 19 per 100,000 tubectomies) of sterilization-related deaths were linked to inappropriate anesthetic practices and inadequate pre- and post-operative care. The evaluation resulted in major changes in program criteria as well as intensified criticism of incentive systems for both clients and referral agent. Subsequently, the death rate for tubectomy was halved, declining to 4.5 per 100,000 performed in 1983 (Cleland and Mauldin, 1987).

Less dramatic examples of the impact of provider competence on the differential acceptability and safety of contraceptive technologies are revealed during introduction studies. In evaluating new IUDs, it is necessary to distinguish the risks associated with the distinctive features of each new configuration, based on problems arising from the techniques of specific providers. When studies of the Levonorgestrel IUD (as yet unapproved by the FDA) began to reveal an unacceptably high perforation rate, investigation found that these rates were associated with specific centers where practice was of an insufficient standard, not traceable to some flaw in the device itself (Sivin, 1988). What have been generally rare in the literature are comparisons between classes of providers or morbidity and technical competence between program settings. Rather, comparison studies have largely been used to qualify new providers (such as nurse-midwives) to undertake procedures that had before been carried out exclusively by doctors. A strong case can be made, however, for more such studies of this kind. US-based studies of the pain and morbidity associated with IUD insertion found predictable differences (which were, nonetheless, important to verify) between the technical competence of inexperienced and experienced providers (Stumpf and Lenker, 1984).

A rare study, nearly ideal in its design, compares two broad areas in which DMPA was introduced in two distinct program settings. Phillips (1988) made clear the value of monitoring technical and managerial capacity of the delivery system when determining the potential reach of a new technology. The author concludes that DMPA's high discontinuation (in the extension areas) and consequent modest demographic impact in the extension areas of Bangladesh are traceable to "the absence of adequate mechanisms to ensure that the climate of care and service quality are generally sound" (Phillips, 1988: 22). In general, it appears that any method that demands a highly sophisticated technique is likely to be underutilized and/or misused in some settings.

Competency-Based Training

Training of providers is not synonymous with quality assurance. Problems of performance of nominally trained staff have led many family planning training agencies to adopt competency-based training where the standard for certification is achievement, whether measured through knowledge levels (of CBD workers or pharmacists, for example) or the mastery of clinical techniques under supervision (for example, IUD insertions, sterilization operations, and implant insertions and removals). Competency-based training requires the trainer to evaluate skill level, not time spent in a training program or numbers of procedures completed. If competency is to be continuously assured after the completion of the training sessions, the provider's knowledge and skill must be regularly used and periodically monitored.

The move to competency-based training is also favorable because it enables classes of providers without medical degrees to provide important services in the field. Midwives and other paramedical personnel can competently insert IUDs, give injections, perform menstrual regulation procedures, and in the future, will likely be able to insert and remove contraceptive implants. When it was first suggested that non-M.D. staff could insert IUDs, a number of case studies were done to compare their competence with that of M.D.s. In Iran, auxiliary midwives with one month's training in IUD insertion, including a minimum of 30 IUDs inserted under supervision, had similar rates of medical removal, expulsion without reinsertion, accidental pregnancy, and removal for personal reasons as did the doctors. The midwives had a slightly lower rate of "removal for personal reasons," which may indicate their superior communication skills (Zeighami et al., 1976).

Monitoring and Data Collection

A mix of monitoring techniques are needed to assess technical competence. A beginning may be to audit the state of clinic records for indications that screening was done, medical assessments made, whether complications were reported and how they were handled, and any other notable medical events (Donabedian, 1980). Another, more specialized form of self-reporting involves the production of case studies—detailed, systematic histories of a limited number of clients presenting a given complaint. Analysis of records can identify the client's background factors that led to the problem, the presenting symptoms, and the provider's initial and sequential responses. This system does not generate comparative data, but provides insight into problems for which remedies may be relatively easy. For example, an account of the case histories of ten pelvic inflammatory disease (PID) sufferers concluded that the ignorance among PID sufferers of the disease's origins, of its treatment, and of its likely path, was not remedied during client/provider interactions (Brown and Waddington, 1987).

These various methods of self-reporting and self-monitoring are valuable. However, assuring the observance of medical standards in most cases requires site visits and supervisory systems where field and clinic-based procedures are regularly observed. Sometimes providers have skills and knowledge but, for reasons not well understood, do not employ their skills or pass on their knowledge effectively. Trainees may know what aseptic technique is, but they may not give it enough importance, and/or are not in the circumstances to observe it. Sometimes providers go ahead with procedures they know to be potentially unsafe, even offensive, to clients. When workers' theoretical knowledge is sufficient for them to pass formal tests or interviews, insufficiencies can only be revealed through observation.

The ICDDR,B Extension Project employed observation as a means to pinpoint problems and improve performance. Government paramedics observed workers' rapport with clients, record-keeping, patient history-taking, and physical exams. Though these workers had received some 18 months of training, the observations revealed that none of the 19 workers observed took a history of the patient or her family, and only a minority washed their hands before physical examination (Nessa and Hurrell, 1985). The World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception published case studies of efforts by their affiliates in 15 developing countries to monitor the quality of care through units designed to operate within the specific management and cultural settings (WFHAAVSC, 1988). In addition to monitoring and observation, in some program settings—especially where contraceptive policies are being developed and reviewed and the introduction of additional methods is under consideration—it may be appropriate to collect reproductive health data on a subsample of clients. To date, very few such studies have been done. Studies of the health of a cross-section of program clients could provide valuable baseline information on women's health (the distribution of infection, sexually transmitted diseases, cervical erosion, menstrual disorders, and nonreproductive but relevant health indicators such as anemia). These data can be used to provide guidance on how and whether to provide specific methods. For example, the decision whether and how to offer the IUD could be positively influenced by the clinical knowledge of the incidence among prospective clients of reproductive tract infections (RTIs) and sexually transmitted diseases (STDs). Such studies could define the magnitude of morbidity resulting from inadequate services: incorrect prescription of contraceptives, improper aseptic procedures, infections, and insufficient follow-up. The results of these studies may also argue for an expanded array of diagnostic and treatment procedures in categorical family planning programs.

Wasserheit et al. (1989), in a study in Bangladesh, turned up 22 percent of almost 3,000 women reporting symptoms of RTIs. "Of the 472 symptomatic women, 68 percent had clinical or laboratory evidence of infection" (1989: 69). Important differences were noted in the reproductive health of users of certain contraceptives: IUD users and tubectomized women were four times as likely to report symptoms and seven times as likely to have examination-confirmed infections as nonusers. However, a number of these problem areas for women, of particular importance where other health services are so poor, might be addressed in revised and expanded family planning services.

Bang (1989), in a study of women in Gadchiroli, a district in the state of Maharashtra, India, examined 650 women (out of an eligible group of 1,102). Even taking into account the fact that "participants" in the study may have had features different from nonparticipants, she reported startling findings—a 92 percent prevalence of gynecological or sexual diseases. Extensive work must be done to confirm her results and to extend this type of baseline study to other areas in the subcontinent. A recent paper from Korea has also suggested very high potential levels of reproductive illness as perceived by women. About 58 percent of the respondents in a rural survey of women of reproductive age reported that they had significant and generally untreated gynecological problems, and 41 percent reported having had abortions (Women's Global Network on Reproductive Rights, 1987).

Punitive Quality

The inappropriate application of medical standards and the medicalization of some tasks, including insistence that they be performed only by specific and highly trained personnel, has led at times to a posture that might be termed *punitive quality*. We see numerous examples of women being denied control of their fertility because of overly restrictive criteria. For example, in one North African country, fully lactating women six weeks postpartum are denied immediate IUD insertion if they admit to having had sexual intercourse, on the grounds that they may be pregnant. In parts of West Africa, the oral contraceptive is only made available after a blood count is completed, and in some cases the client's request is reviewed by several physicians. In the "dubious practice" category, the bleeding patterns of hormonal contraceptive users are sometimes treated by giving estrogen or other drug regimes. In some parts of the world, women receiving sterilization are given a general anesthesia, when local anesthesia often is safer, provides adequate pain relief, and requires a shorter recovery period. Sometimes the barriers to service are justified by the phrase, "We want our women to have the very best care." Such claims should be examined when they effectively remove access to critical contraceptive care except for the most persistent or well-off.

Conclusion

The disparity between the articulated, often Western-based standards for technical competency and what is found in the field must be addressed through quality assessment. It is possible that the standards are not realistic or are inappropriately defined. For example, if one form of sterilizing procedure is not available, providers need to think about realistic alternatives. When a real risk exists that needles, trocars, and other clinical devices will be reused—and such reuse is dangerous—field staff must forthrightly deal with that risk by either rejecting altogether such behavior, or providing instructions to prevent it.

The technical competence required of many workers may be beyond their capacity. Perhaps a tiered system is in order, where staff are required to perform only up to a certain level, and then refer clients on to the next level, as needed. Interpersonal care and technical competence must come together, and providers must understand the importance of observing safe clinical standards. When only 9 of 19 workers wash their hands before inserting an IUD, it is reasonable to question whether their training included an appreciation of health consequences or the clients' needs.

Interpersonal Relations

The "interpersonal relations" element in the framework has been separated from the information given users because it is defined as the affective content of the client/provider transaction. It is this dimension, apart from the accuracy of the information given and the degree to which it is comprehended (important as it is), that may strongly influence clients' confidence in their own choices and ability, satisfaction with the services, and the probability of a return visit. What is desired is positive and productive exchange as perceived by the client. A recent review of counseling suggested that the desired attributes of the counselor were those of understanding, respect, and honesty (Population Reports, 1987). The client/provider contact should be characterized by two-way communication and question-asking, and flexible guidance (as opposed to authoritarianism) on the part of the provider. The desired outcome from this transaction, from the point of view of the provider, may be that the client reports a belief in the competence of the provider, trust of a personal nature, and a willingness to make contact again themselves, or even refer others.

Another affective dimension of the family planning worker's role is to *compensate for the technical limits of contraception* or logistical problems in accessing services. Empathetic information-giving may be as important as accuracy in allaying negative feelings about, for example, an implant insertion, the care with which diaphragms must be used, and so forth. In circumstances where women have to travel for special services about which they have some fear (like sterilization), a fieldworker accompanying the client compensates, in effect, for her discomfort with an unknown procedure. The workers' ability to discuss their own contraceptive experience or the ability to point out a healthy community member who is happy with a method responds to the client's reasonable worry: What will this method do to me and my health? The counselors provide, in effect, a guarantee of the technology by their presence and manner of communication (Simmons et al., 1988).

In many settings, the counselor cannot empower the client to make her own reproductive decisions unless she extends her intervention to the client's personal situation. For example, Simmons et al. (1988) document in Bangladesh the vital role of the family planning worker in helping women manage male authority in the family and in the community. The fieldworker's role is often one of ally and mediator, urging women to find their own voice and express themselves, and providing them with ideas they can use in arguing for their right to practice contraception. This task, for which workers are not formally prepared, is essential when women are in very inferior positions in the family and fear the consequences of unsanctioned contraception, which can include divorce or abandonment.

In assessing client/provider relations it is difficult, but essential, to separate the information-giving role (discussed above) from the counseling role. Reviewed below are scarce and generally small-scale qualitative studies of client/provider transactions, which unveil, analyze, and, in some cases, "grade" the emotional content of this interaction from the client's perspective.

Clients' Feelings

Mernissi (1975), in one of the early explorations of women's feelings about contraceptive services, described the indignities Moroccan women were asked to suffer, which included taking off their underpants and waiting in the hall for a pelvic examination. Scrimshaw (1976), in a series of studies of family planning services in Latin America, describes insults to women's modesty and sense of privacy resulting from having no separate interviewing rooms or curtains in examining rooms.

Other early literature that sought out factors that improved the workers' effectiveness and acceptability tested the hypothesis that clients were most comfortable with workers who resembled them in basic characteristics such as gender, marital status, and social class (the principle of homophily). Though this principle does not hold invariably, Repetto (1977) and many others have found positive support for it in a number of settings. Similarity between providers and clients may yield not only more contentment on the part of clients, but also different program outputs.

A recent review of worker performance in Bangladesh revealed different patterns of exchange between male and female workers and their clients. Female workers spent more time with clients and were more likely to recommend a range of methods and less likely to push women toward sterilization (Phillips et al., 1986). Research in Colombia indicated that nurses were more likely than physicians to change the methods of their patients. In addition, they were significantly more likely than physicians to keep their patients on conventional methods or even switch clients to "less effective" methods (Einhorn and Trias, 1978). It may have been that female nurses identified with their clients and trusted them to practice self-employed methods efficiently, and/or that they were at ease discussing the sexual dimensions of the use of barrier methods. The nurses' approach did not compromise use-effectiveness. In this particular study, the clients of physicians and nurses alike had high (85 percent and 84 percent, respectively) continuation rates at six months and only 3.2 percent of those in the physicians' group, compared with 2.7 percent of those in the nurses' group, became pregnant in that time.

Schuler et al. (1985) undertook a study in Nepal that evaluated the client/provider transaction, separating the accuracy and completeness of information given from the attitude and bias of the provider. In this study, "simulated" clients of different caste groups were asked to visit family planning providers. An unexpected result was the reluctance of the lower-class simulated clients to either make initial contact or return to services. They were fearful of the general service-providing system and vulnerable to the assaults on their status during their simulated interviews (in one case finding it difficult even to obtain the names of available contraceptive methods); members of this caste expected poor treatment and when they received it, were reluctant to criticize. Interviews were scored according to the degree of courtesy, consideration, attentiveness, and respect shown the client. Relevant behavior included greetings, whether the client was asked to sit down, the forms of speech with which he or she was addressed, and the ability to participate in a two-way dialogue, asking questions. The authors found a strong bias in the types of methods their "lower-class" clients were recommended; they were advised against using condoms and were directed to pills, IUDs, injectable contraceptives, and sterilization.

Among the dimensions of the client/provider relation in Latin America reviewed by Gay (1980) was the style (as opposed to the content) of information-giving. Rather than employing the time available for interpersonal exchange to reassure the client and make her more comfortable, the providers in effect undermined the client's confidence: "Clients are lectured on contraception with few opportunities for questions. The talk may consist of a morality lecture rather than a well-needed and valuable discussion of possible contraceptive side effects" (1980: 28). A study of family planning clinics in Honduras quoted a client who had been asked for her ideas about how to improve services. She said, "There should be more understanding for us humble people because we go there with great fear" (Mundigo, 1973: 14).

Management's Role in Promoting Better Interpersonal Relations

The examples given above, drawn from the far too limited research on client/provider transactions, affirm the importance to clients of privacy and observance of their modesty, bilateral interpersonal exchange without condescension, and some measure of identification between themselves and the provider. A caring attitude is important on the part of all personnel with whom clients deal. This caring attitude, or lack thereof, is not the product solely of the individual provider's personality. Rather, the ability of all classes of providers in the system to communicate well with clients is influenced by a whole stream of managerial decisions, beginning with the establishment of provider norms, training, job descriptions, structure of supervision, and rewards. Simmons et al. (1986) and Koblinsky et al. (1987), studying client/provider transactions in Asia, identify management and political factors that encourage or discourage effective interpersonal connections. In the two Matlab experiments mentioned earlier, contributing to the greater health and fertility impacts of the second experiment was an explicit change in program focus to what was defined as a *client orientation*. Workers were instructed to find solutions with individual women. This was accompanied by management decisions to increase the frequency of contact with clients, innovative record-keeping systems, and better supervision.

In contrast, workers' ability to respond sympathetically on an individual basis to clients can be undermined if they are working under the pressure of targets to attain demographic goals. The tasks workers are thus assigned often prove unreasonable. In early CBD projects, the worker acted as little more than a delivery service with a minimal communication role. The interpersonal content of this approach was probably best described in the case of an Egyptian CBD project, which boasted that each household contact required less than three minutes. Under target systems, the worker's service role can easily become secondary to meeting a numerical quota of specific method acceptors. An experiment undertaken in 1983–84 in the district of Rajastan State, India found that the target orientation was not conducive to systematic program operations. An innovative experiment was implemented in which workers analyzed client data and classified their clients into four groups, each requiring a distinctive approach. Though this approach did not directly correct the demographic ideology underlying the program, managers encouraged workers to understand more about clients' individual outlooks (Giridhar and Satia, 1986).

Similarly concerned over the impact of targeting systems and worker performance, some experiments were undertaken within the extension areas of Bangladesh to see if a new record-keeping system could improve the client orientation of workers. It was judged, however, that unless the target system was revised, the reorientation of staff could have only limited effects (Koblinsky, 1987).

Quantity and Quality of Care

The National Academy of Sciences' review of family planning effectiveness (Lapham and Simmons, 1987) identified the quantity of provider/client contact as another powerful determinant of the quality of care. The review concluded that in commercial, clinic-, and community-based systems alike a strong positive relationship exists between quantity and quality of contact. High levels of contact in commercial systems are welcome but largely unplanned. Over time, a relationship may spring up between druggists and their contraceptive customers that extends beyond supplying methods to providing broader health advice (Mitchell, 1984;

Assad and Katsha, 1981). The reverse is also true—because of druggists' and other personnel's role in giving informal health care, some seek them out when they first think about fertility control.

Community-based distribution systems have largely been devised to increase the accessibility of services. Depending on the worker/client caseload, the amount of time available for transactions may be very limited. For example, a study of work routines in Bangladesh found that even under the management's best projections, workers might have on the order of 11–14 minutes with each woman in the three-month period; the actual time proved to be closer to eight minutes because low worker densities meant that travel consumed a larger portion of the day, and many workers actually work fewer hours than scheduled (Koblinsky et al., 1987). (This and other analyses in Bangladesh were key in promoting the policy of doubling the number of female family planning workers so that they could provide more intensive service.) A review of programmatic and social determinants of client relations in South Asia (Simmons et al., 1986) concluded that the quantity of contact in the Bangladesh project under study (in the 1980s) was substantially higher than the India project study in the 1970s, with the result that higher worker-to-client ratios correlated with higher prevalence rates. Supervision, reward, and control systems all had a substantial bearing on client/provider transactions.

In the clinic setting, irrational or unorganized "patient flow"—that is, the efficiency with which patients are received, examined, and "flowed" through the system—can create or exacerbate poor interpersonal relations (Hudgins and Merino, 1988). This, in turn, may spring from poor scheduling of appointments, too few clinic hours, too few staff, and the misuse of some workers' time. Gay (1980) compiled alarming information on patient flow from multiple programs in Latin America. She observed, among other things, that in a Central American clinic average waiting time was of three hours and forty-five minutes (and up to six and a-half hours) for a first-time client, and one hour and fifteen minutes (and up to four hours) for a resupply client. On the other hand, the amount of time spent being served was astonishingly brief. Doctors typically saw women for a few minutes. One study in Tobago revealed women spent seconds rather than minutes with the doctor; 34 women received internal examinations in 25 minutes—including four IUD insertions and prescriptions for three cases of pelvic inflammatory disease (Cross and Arbor, 1977, as cited in Gay, 1980).

Sterilization camps in India and Nepal have also recorded astounding case loads per operating physician. Though the standard of care established suggests no more than 40 procedures per day, some physicians do up to 80 to 100 cases per day. Both provider competence and the quality of the provider/client transaction must be seriously compromised by such practice.

Conclusion

Despite all these negative accounts, many workers remain who are trusted by their clients even when they have irregular contraceptive supplies, too little time, and receive insufficient salaries. Yet, the service system has to develop understandable, observable, and affordable standards of interpersonal interaction, and alter program factors to favor it. The process for providers is perhaps two-tiered. In well-established programs, diagnostic work that begins with the client's perception of services is in order. Some of the techniques used to date include in-depth discussions with staff at all levels regarding their perception of the interpersonal process with clients, observation of client/provider transactions (Simmons et al., 1988), "simulated" clients (Schuler et al., 1985), patient flow studies (Hudgins and Merino, 1988), focus groups with clients (Folch-Lyon et al., 1981), and exit and post-service interviews. Much work needs to be done to devise appropriate questions that are specific enough and provide for scales of response (Huntington, 1988). Social marketing programs might explore the use of intercept studies (Green, 1988) in learning more about the client's experience of brief, but crucial, commercial transactions.

These sorts of studies will ultimately reveal a picture of what needs to be fixed from the client's perspective, although providers' knowledge of their own system and points of intervention will be vital to solving the problems presented. Among the likely interventions available are the revision of training approaches, the development of explicit criteria for interpersonal interaction, analysis of workers' case loads and distracting work pressures, increasing supervisory support for workers' interpersonal performance, and so forth. Progress in this area will rely upon program managers' willingness to orchestrate the interpersonal dimension of care as fervently as they do the technical dimension. For many clients, being treated badly is worse than receiving no care at all.

Continuity and Follow-up

In the early phases of family planning program development, most programs were clinic-based. Clients who did not reappear for their return visits were, in the best of these programs, recontacted by an outreach worker and encouraged to return. At the present time, though many women continue to be served by clinic-based systems, few of these programs conduct regular follow-up and perhaps more men and women in the world are served through commercial and CBD systems. Thus, the term "follow-up" has a somewhat dated and impractical ring to it for some, but the concept underlying it remains valuable.

Continuity of Use versus High Acceptance

Relevant to the operations of clinic-, commercial, and community-based systems is the broad objective of encouraging continuity of care to assure that after the first contact with a contraceptive provider, the trail does not end. More philosophically, a program's willingness to establish continuity or follow-up mechanisms is one measure of its longer-term commitment to individual welfare. The concluding discussion in the National Academy of Sciences report expresses it this way:

> Ultimately, we will propose that the test of quality care—the basis on which the client/provider transaction should be judged—lies not with its purely demographic consequences (e.g., measurable decline in fertility) or even in the maintenance of high levels of contraceptive use per se, but in the extent to which clients feel they have established a reliable relationship with a trusted provider and have achieved some substantial measure of safe, effective, and comfortable control over their reproductive capacity (Lapham and Simmons, 1987: 517).

The strongest practical argument for promoting continuity of use is the consequences to individual programs and national efforts of the failure to do so. Many family planning programs are designed with recruitment of clients more in mind than maintenance of use. Where demand for contraception is well mobilized, such an approach may not be fatal. But where modern contraceptive use is still an innovative behavior, the neglect of the pool of users has very serious consequences for overall program performance. Jain, in analyzing the interplay between acceptance and continuation rates, compares the consequences of high acceptance and low continuation with low but steady acceptance and high continuation. Using modeling to discern the relative impact of high acceptance versus high continuation, he finds that "programs can achieve better demographic results when they concentrate on a small number of annual acceptors and provide them with good care to enhance their satisfaction and thus to improve continuation rates, rather than trying to recruit a large number of acceptors at one time and not take care of them" (Jain, 1989: 6).

A handful of long-term follow-up studies have been conducted to give us a view of one-time clients' ongoing ability to control their fertility years after their first contact with formal delivery systems. Does discontinuity of program contact mean clients are no longer practicing contraception, are exposed to unwanted pregnancy, and/or have changed their fertility intentions? A classic follow-up study, conducted in Taiwan, charted the history of women who had originally had IUDs inserted in the late 1960s. Thirty months after insertion, only 28 percent still had the original device in place. Twenty-seven percent were not practicing contraception but had not become pregnant in that interval, and only 8 percent had become pregnant and carried to term. Former IUD clients had found other solutions in the form of other methods (though in limited supply at that time) and the use of abortion services, and, for a number of women, life circumstances had changed in the interim, leaving the client unexposed to pregnancy (Freedman and Takeshita, 1969: 347). The Philippines National Acceptance Survey (Laing and Alcantara, 1980) recorded all method continuation rates of 44 percent at 24 months and 21.3 percent at 60 months. Reviewing the reasons for such dramatic dynamics, the study found that 45 percent of discontinuation of the first method and 30 percent of discontinuation of the last method used was attributable to unmanaged side effects. Thirteen percent of those who discontinued use of first methods and 30 percent who discontinued use of the last method ended use when they became accidentally pregnant.

Role of Program in Short-Term Continuation

Shorter-term studies of "lapsed" users point to poor initial contact, ignorance of side effects and the possibility of switching methods, and inadequate follow-up as primary reasons for terminating the use of specific methods or contraception altogether. In general, these studies find very little discontinuation (within 12 months) traceable to changes in clients' intentions. Mundigo (1973) describes the follow-up of 158 women who had missed their return appointments by one to three months in clinics in Las Crucitas, Honduras. Twenty-six percent could not be recontacted because of sketchy information about their addresses. Only 85 women were found and, of these, 11 percent had become pregnant and 13 percent had been abandoned by their husbands in the intervening three months. Less than half of the 85 women contacted returned to the clinic, and only 30 percent of those who cited their concerns about side effects returned.

A post-family planning acceptance study in St. Vincent and St. Kitts-Nevis found that among women more than three months late for their last appointment, three-fourths in St. Kitts and 40 percent in St. Vincent were exposed to pregnancy. One-third of those who discontinued in St. Kitts, and one-fifth in St. Vincent, cited problems with their method. Another large proportion cited problems with clinic services and treatment by staff as deterring recontact (Bailey and Keller, 1982).

A recent study in Zambia (Whittaker and Coeytaux, 1987) indicated that a large proportion of the substantial number who discontinued (75 percent of users at the end of 12 months) could attribute their lapsed status to problems with the clinic, the availability of supplies, or the methods, all of which could have been improved through better management of resources.

Paralleling our poor knowledge of long-term contraceptive use dynamics is a general scarcity of information about the impacts of *specific* follow-up efforts on clients' behavior. A study in metro Manila of outreach versus non-outreach areas (both of which extended around clinic-based facilities where acceptors usually lived) recorded a higher contraceptive prevalence rate in the mid-60s compared to one in the mid-50s in the non-outreach areas (Zablan, 1985). The author also observed problems with the outreach system, including its inflexibility, which increased its cost in relation to its effectiveness. A family planning follow-up study conducted in Botswana in the late 1970s (Stephens, 1978), in response to a 65 percent discontinuation rate, found a positive correlation between active home visiting and compliance with follow-up health care.

An experimental program conducted in St. Vincent and The Grenadines (in response to the findings discussed above in Bailey and Keller, 1982) sought to reduce discontinuation by increasing clients' knowledge about contraceptives and their possible side effects, and by developing in clients and providers an awareness of alternative brands and method switching as preferable to abandoning contraceptive use altogether. The intervention designed gave additional training in side effect management counseling to community workers in two treatment areas. Whereas contraceptive prevalence at one year was not markedly different between control and treatment areas, clients' knowledge of contraceptives had notably increased, especially in the most intensive treatment area where more than 80 percent of the respondents knew about the pill, injection, IUD, female sterilization, and condoms. In the control area, a higher proportion of women (26 percent as opposed to 17 percent in the most intensive area) had experienced problems with their current method (Russell-Brown, 1985). A recently completed study in Mysore, India of 400 women who had IUDs inserted during the 1983–86 period found that women who discontinued IUD use within 12 months were significantly more likely to have received no follow-up than the average continuer (Prabhavathi and Shenshadri, 1987).

Improving Continuity of Use in Community-Based Programs

The studies discussed in the preceding section were conducted in program settings where clinic service is the focal point and field agents are employed as a supplementary service delivery approach. In programs where first contact and continuing service are to be provided through community-based links, the means available to encourage continuity of use are different. In these systems, neighborhoods rather than clinics are the service sites. In some systems the worker repeatedly contacts all women of reproductive age in a given area and in others the worker makes one pass at all the eligible households and recontacts only the acceptors for resupply purposes. This latter approach does less to generate a new base of users but may result when the density of workers to clients is so high that resupply of users is the minimum the worker can accomplish.

Community-based programs may have to approach the issue of continuity of care on two levels: that of the individual user's contraceptive practice and promoting a consistent and trusted relationship between fieldworkers and the community. The earliest community-based systems were designed neither to constantly support individual clients nor pick up clients on subsequent rounds. Continuous visiting to the same area, including to women who were not acceptors on earlier rounds, is not the same as follow-up, but a predictable worker visiting pattern is an excellent means to support ongoing clients and to pick up women whose need status has changed. In some parts of the world it is not unusual to find up to 30–50 percent of the women of reproductive age pregnant or lactating. High fertility rates, the instability of partnerships, and spousal separation owing to migration all contribute to sometimes rapid changes in clients' need status over the course of a year.

Successful field projects such as Concerned Women for Family Planning in Bangladesh rely upon frequent visits. An evaluation of this program cited factors responsible for its apparent success and included among them the numbers of methods available and the pattern of door-to-door service delivered on a regular basis (Pyle and Khair, 1982). An experimental CBD project in Morocco employed one to three visits to women who accepted contraceptives initially and those who did not in an area where contraceptive use was already relatively high. A significant number of women who did not accept on the first visit became acceptors on a second visit. The evaluation found that "revisitation is a very valuable procedure which added additional acceptors and likely contributed to the higher continuation rates than the single round survey" (Ministry of Public Health, Government of Morocco et al., 1981: iv). Through the observance of a predictable visiting schedule, the worker becomes a *reliable institutional factor* in women's lives and a source of information and help when they need it. (For elaboration of this concept, see Simmons et al., 1988.)

Making the Best Use of Existing Resources

Though clinic- and community-based programs may need additional resources to achieve the highest levels of continuation, more efficient use can be made of existing clinic and field-worker time. Patient flow studies often identify means both to increase the clinic volume and to decrease client waiting time (Hudgins and Merino, 1988). For example, clients seeking resupply or the answer to a quick question can be served separately from those having their initial intake. In field-oriented programs the density of workers and their distance from work sites and supervision are key determinants of the time spent in face-to-face contact with clients. Areal studies of contraceptive coverage underscore the strikingly low quantity of contact reported in areas where household visiting is meant to be a central program strategy. Misra et al. (1982) described a home visiting program in India that fell far short of its goals:

> Despite the existence of this program for a number of years, and the development of a work plan that should have permitted virtually every eligible couple to have been visited by at least one government worker on the question of family planning, fewer than 10 percent of the female respondents and less than 15 percent of the male respondents indicated that this had been the case (Misra et al., 1982: 386).

In the Philippines, a study of the effectiveness of outreach found that only 21 percent of the continuing users and 14 percent of the dropouts recalled a visit from an outreach worker (Laing and Alcantara, 1980). The shortfalls are attributed to travel time and substandard effort; many hours per week were unaccounted for by service effort. However, in the Philippines, as elsewhere, managers are also responsible for misusing workers' time by requiring them to fill out lengthy, redundant forms, largely unrelated to their care-giving role (Phillips et al., n.d.).

Clark et al. (1988), in an assessment of Bangladesh government health and family planning workers, studied not only rates of contact but the content of visits. In the study areas a great majority of women of reproductive age had had at least one visit and a substantial number had had more than two over one year. Between 44 and 84 percent of the visits by female workers and 15–90 percent of those of males involved some sort of substantive health discussion or transaction. However, only 8–12 percent of female welfare assistants' visits—those whose central concern was family planning service delivery—resulted in giving tangible service. An outstanding question worthy of further research is whether and how clients value these visits. Are the transaction opportunities with government workers valued by socially confined rural women?

The third major family planning system—commercial distribution—has made only limited attempts at follow-up, largely for research purposes. Some feedback loop has been established in some programs (notably Sri Lanka and Egypt) between the pharmacy and the clinic. In the case of Sri Lanka, at one time women who purchased oral contraceptives were given a list of physicians with whom they could check should they have difficulties. (Sri Lanka has a particularly low population–doctor ratio.) The social marketing program in Egypt allows women to buy IUDs, and they, too, are expected to make subsequent contact with a private physician or clinic. Intercept studies (interviewing users as they exit from purchasing contraceptives) have addressed themselves to brand loyalty and issues of cost, but have given less attention to the dynamics of continued use.

Conclusion

Over the last three decades, since the notion of follow-up was first formulated, the characteristics of programs and their clients have changed, in some cases dramatically. More and more women around the world are superficially knowledgable about contraceptives. More and more clients overall are self-referred and bypass formal medical advice altogether when initiating use. How can the media be used to inform the public, to support responsible self-care, and to direct widely dispersed clients to appropriate services? How can underfinanced programs use existing resources better to assist clients in managing their own fertility over time?

Supporting continuity of use among all clients may remain a desired goal, but priorities for specific follow-up must be set. Indiscriminate revisiting may waste time and undermine workers' morale. Distinctions should perhaps be made between the needs of a couple who state they want more children, a long-term established user of a provider-dependent method, and a young, new user of a self-employed method. The concept of *new* clients could be extended to include all those who are within their first year of use with a new method (not those who only made an initial visit). These individuals might benefit from orally and visually reinforced educational messages and receive specific follow-up methods early in the method-adoption process.

Where the health infrastructure is very weak, and services and workers scarce, follow-up visits for family planning might be integrated with those for other purposes. Stephens (1978) suggests the use of an integrated home-based record-keeping system wherein the health status of both adults and children is recorded. Such a procedure would reinforce the clients' rights to information about their own health and may be a practical solution. Stephens also reported that, in Botswana, 96 percent of the adults reliably retained their records and 99 percent retained those of household members under five years of age. Another means to serve women living in remote rural circumstances may be to network them, with their permission, in some way so that new users would be given the names of other women in their area using the same method. This could assist them in resupply and support.

Even without a heroic effort to win recontact, programs should focus on assisting clients in more effective self-care over the long term. Mass media—notably radio, displays at purchase points for contraceptives, package inserts, and so forth—could be employed to remind clients about the health dimensions of contraceptive use, such as having their IUDs or implants checked, discouraging pill use among heavy smokers, and the like. Effective follow-up and support of clients may demand some new resources, but they also require a stronger marketing sense and innovative thinking.

Appropriate Constellation of Services

Of all the elements in the framework discussed here, judgments about the adequacy of the "appropriate constellation of services" is least universal and most conditioned by context. Even within fairly limited geographic locations, contrasting configurations of services may be acceptable and even desirable. The possibilities are bounded only by clients' needs and managers' resources and imagination.

Given the possible variations, the evaluation of the appropriateness of the constellation of services is particularly value-laden. There are also several levels to this assessment. The most rudimentary level of judgment is whether the services are provided adequately within the articulated spectrum of the program. A second level of judgment is whether the service constellation is appropriate to the needs of the client population. If programs have determined to go beyond the conventional boundaries of family planning, to which of the many social forces and resources constraints have they responded? Experiments in expanding the constellation of services extend from the integration of conventional reproductive health services (MCH/FP) with less regularly offered, but vital, adjuncts—like the diagnosis and treatment of RTIs and STDs—to programs with an explicit social purpose. The latter category includes programs that use health services for women as their base but view the empowerment of women as an overall goal.

Simmons and Phillips (1987) analyzed the contrasting results of "vertical" (contraceptive and sterilization services only) and "integrated" programs—the latter combining family planning services with maternal and child health care services. They concluded: "Client populations have responded well to both integrated and vertical services. The lesson appears to be that people desire good services, irrespective of their specific combination" (1987: 204). While centering their evaluation on the impact of different combinations of services on family planning effectiveness, they call for a more detailed view of integration, focusing attention on the strength of the service-providing organization, however configured, and the impact of the constellation of services on worker performance as well as on client responses. Thus, a nominally "categorical" program (the Matlab Community Distribution Project or CDP) is faulted because of its limited quality and, therefore, limited acceptability, rather than for a basic flaw in the notion of vertical services. In contrast, the Family Planning Health Services Project (FPHSP) is not an unalloyed success because, the authors point out, it is selectively integrated, and some of the interventions perform badly, both in terms of negative effects on contraceptive prevalence and on organizational development.

The salient point of the Simmons and Phillips conclusions for the present discussion is that the appropriateness of the service constellation begins with an analysis of its competence. At the very least, any family planning or reproductive health service should include a sufficient standard such that immediately related health screening that bears on the prescription of contraceptives is available. Referring to the earlier discussion on technical competence, given the scientifically documented tendency of some contraceptives to either cause or exacerbate reproductive tract infections, including STDs, much greater attention should be paid to developing and deploying low-cost diagnosis and treatment of STDs within family planning service programs. If the broad credo of family planning services can be paralleled to that of medical doctors—"first do no harm"—family planning services should make every effort to be sure they are taking reasonable steps to improve the reproductive health of their clients.

Beyond assuring basic medical competence, programs should seek to learn how clients view their health and what they believe are the most pressing health needs directly related to their contraceptive use. Both practitioners' and researchers' experiences show that, in most settings, women see a close interrelation of all their reproductive functions; thus, it seems perfectly reasonable to combine prenatal advice, delivery, postpartum services, and diagnosis and treatment of gynecological infections. Mothers also view their children's health as an extension of their reproductive well-being (Better Health for Women and Children, 1987).

Germain (1987: 22) pulls these strands together in her definition of a reproductive health approach (as distinct from the approach underlying most FP and MCH programs) that would seek to enable Third World women to:

- regulate their own fertility safely and effectively by conceiving when desired, by terminating unwanted pregnancies, and by carrying wanted pregnancies to term;
- remain free of disease, disability, or death associated with reproduction or sexuality;
- bear and raise healthy children.

Though at this point in history few programs can perform all of these functions, such a concept provides a framework around which a broad service system could be organized.

Clients' views on the appropriate constellation of services can be gathered indirectly through analyzing textual accounts of their conversations with workers. Simmons et al. (1988) identified the scope of demands upon workers by recording conversations in the field. They found that service dialogues were sometimes thwarted because workers could not or would not respond to the client's salient crisis—the ill health of a child. Also, female clients asked for substantial assistance in overcoming male opposition to contraceptive use or fears of contraceptive technology. The responsive worker might devote considerable effort to convincing patriarchal authorities to permit contraceptive use, and traveling with a client for a distant sterilization or IUD insertion. The ICDDR,B program in the extension areas is using these conversations to discover clients' expectations of the workers' abilities. Where a discrepancy is detected between the workers' training, capacity, materials, and work incentives and clients' expectations, programs have an opportunity to improve the match.

If the first question to be asked in reviewing the service mix is, "Are we doing our job well?" and the second is, "Are we reasonably meeting our clients' expectations?", then the third question is an optimistic corollary of the second: "Is the program imparting to its clients a more conscious interest in their own health and other aspects of their well-being?" For example, a family planning program guided by and successfully transmitting the notion that women have the right to control their fertility is likely to bring to the surface women's interest in exercising power in other parts of their lives. Programs committed to responding to clients' perspectives, in this case women clients, may find a rationale for political involvement in women's rights issues (including the provision of safe abortion services), supplying clients with referrals for legal advice, economic services, or in some cases even developing economic adjuncts to their health service work.

Finally, a provider evaluating the overall service approach needs to be sensitive to another dimension: timing. The reproductive health approach articulated by Germain (1987) suggests a natural but intricate sequence of family planning, reproductive, and early childhood health services in a woman's lifetime. The basic document from the International Conference on Better Health for Women and Children through Family Planning puts it this way: "Human reproduction is a drama which begins with sexual intercourse, continues through pregnancy, reaches its climax in labor and delivery, and is only complete when the newborn baby has passed through the vulnerability of infancy and early childhood" (Better Health for Women and Children, 1987: 5–6).

In seeking to bring to life the meaning of "appropriate constellation of services" in this section some examples of soundly configured services are offered, and three natural linkages are highlighted: the linkage between contraceptive use and sexuality, between the mother's and child's needs in the immediate postpartum period, and between pregnancy termination and pregnancy prevention.

Sexuality and Contraceptive Use

A recent experiment to focus more attention on sexuality concerns in family planning programs was undertaken in a large public maternity hospital in Salvador Bahia, Brazil. The project offered all reversible contraceptive methods except the vaginal suppository, and referred clients for that method and for voluntary sterilization. It provided information and opportunities for clients to raise questions about human reproduction, contraceptive methods, and sexuality. Unusual emphasis was given to the counseling component. A service visit included four parts: individual pre-consultation with a nurse, group education discussion, medical exam and consultation, and post-consultation interview period. Though this comprehensive approach with extended education required new clients to arrive between 7:00 and 8:00 a.m. and remain for four to five hours, the service picked up tremendous demand based on word-of-mouth. Each day, 10–15 new family planning users were seen. The program ultimately was discontinued owing to political factors, but not before some evaluation had been done. Despite the length of time that clients had to spend at the hospital, they did not feel ill-served. On the contrary, clients highly valued the educational sessions, particularly the information on sexuality, as nearly half of them reported significant problems in their sexual lives. It was, in fact, the program's willingness to deal with this intimate concern that attracted them (Shepard, 1986).

A clinical research group in southern Brazil evolved a slightly different model when staff found that about 30 percent of the female family planning clients spontaneously mentioned sexuality concerns in their intake interviews. In a follow-up service experiment, 500 women were offered a series of four sessions of group sexuality counseling. Eighty-five percent responded favorably and attendance was very high. The 15 percent who did not choose to attend the sessions cited travel time, not the value of the program, as the reason (Goodson et al., 1988). With regard to contraceptive practice, 52 percent believed initially that their problems with sexuality were related to their method use. At the conclusion of the four-session program, only 12 percent saw such a relationship.

Sexuality concerns may be heightened in Brazil, but what is likely is that the increasing openness of the society, of social researchers, and of some providers is allowing concerns to surface that are characteristic of women all over the world. The paucity of information about Third World women's and men's sexuality concerns, and the unwillingness or inability of family planning services to deal with them, is often striking. Family power relations, sexuality, and contraceptive practice are intimately related; little information has been gathered from women and men in developing countries about their sexual feelings or practices. An indirect perspective on sexuality in developing countries was afforded through focus group sessions held in Mexico City in 1978, in which some women reported "a deep sense of depersonalization, humiliation, and physical dissatisfaction caused by their husbands' treatment during sexual relations" (Folch-Lyon et al., 1981). Other focus groups, conducted to learn more about natural family planning, have found that some women view the long periods of abstinence as "good," enjoying their removal from sexual availability (Jennings, 1988). For others, the required abstinence or change to noncoital sexual practice is a hardship that leads to abandonment of the method (Sharma and Sevick, 1988).

Other research, into clients' perspectives on the NORPLANT® implant system in Brazil, not only reported a high proportion of women experiencing menstrual irregularity, but further confirmed that most experiencing this bleeding (79 percent) indicated that bleeding discouraged sexual intercourse because of a fear of venereal disease, pain, infection, and a sense of modesty (Hardy, 1987). In the western countries, the role of sexual feelings has been increasingly acknowledged in contraceptive decision-making and use-effectiveness (Joffe, 1986; Spain, 1987). This acknowledgment has been translated into enhanced training for some family planning counselors. This approach can be fruitfully extended to Third World programs.

Postpartum Services

The definition of the appropriate services for mother and child in the immediate postpartum period has seemingly already been answered through the nominal integration of maternal and child health services and the International Postpartum Program (IPP) (1968 to 1970). Current postpartum programs rely upon the conventional wisdom of an earlier time, which accorded little importance to womens' views, the interaction between lactation and contraception, and the nature of the mother–child bond. The IPP posited that women exhausted from a recent delivery were ready to avoid a similar experience in the near future. The IPP itself found that women who had just delivered a baby might be interested to hear information about contraception, but that almost half of the contraceptive acceptors in the non-US sample took up contraception between the first and the twenty-fourth month postpartum, with a sharp peak at about six months (less than three months, 9 percent; four to twelve months, 49 percent; thirteen to thirty months, 27 percent; thirty months, 15 percent) (Zatuchni, 1970). A more recent exploration of adolescent postpartum clients found that their memory of the encounter with the family planning counselor was vague and in most cases nonexistent. Whereas many more low-income women are being attended during delivery, and many of these are delivering in hospitals, hospital stays are increasingly short (counted in hours) and the client is subject to numerous hospital protocols in a period when she may have a sort of amnesia (AMES, 1987).

Assuming women are ready at some point, but perhaps not immediately post-delivery, to receive information about contraceptives, the question then becomes how best to integrate maternal and child health services used by women. Six-week returns for mothers alone, for check-ups, often fall below the 50 percent level. This figure can be even worse for very young women whose contact with the service system is tenuous, or for high-parity mothers who feel they are too experienced or too pressed to seek official assistance. In general, women give priority to caring for their newborn rather than for themselves. However, a maternity hospital in Sfax, Tunisia, where a high proportion of the babies are delivered in that district (11,000 per year), has achieved a return rate of about 85 percent by combining the maternal postpartum visit, contraceptive care, and well-baby and immunization visits into one day. That day—the fortieth day after delivery (roughly six weeks)—also has significance within the Moslem culture (and others, as well), and is a follow-up appointment that women (and, increasingly, their husbands) are happy to keep (Coeytaux, 1989).

A further difficulty in most postpartum programs, even where contraception is offered in a manner sensitive to the timing and expectations of clients, is the medical policy content. Indeed, so absent was a concern with lactation and contraceptive interactions in much of the 1970s, that indiscriminate use of oral contraceptives in recently delivered women promoted by some contraceptive distribution programs may actually have increased the birth rate while inadvertently harming the health of infants. Winikoff et al. (1987), after conducting a review of common, and often misguided, postpartum contraceptive advice, developed a sourcebook for clinicians. After reviewing numerous studies of the fertility of lactating women, the authors concluded that, "While it is impossible to predict the exact week or month a breastfeeding woman ovulates, as long as she is fully breastfeeding and not menstruating, the chances of conceiving prior to three months postpartum is very slight" (1987: 12). The sourcebook provides specific protocols for the use of different contraceptives (and indicates the need for prohibiting use of some contraceptives during the lactation period), including the appropriate timing of their use.

Pregnancy Prevention and Pregnancy Termination

Putting aside political and ethical controversies, the service relationship between pregnancy prevention and pregnancy termination bears discussion. Many adolescents and numerous, but undocumented numbers of Third World women are motivated to make their first visit to a family planning clinic because of a fear about unwanted pregnancy or anxiety about their current pregnancy status. For example, when the New York State abortion law changed in the early 1970s, the caseload of Planned Parenthood of New York City doubled. However, pregnancy termination clients contributed only part of the increased caseload. Of 100 women coming to the clinic seeking pregnancy termination, as many as 40 percent were not pregnant and were able to be served with contraception. The pregnant 60 percent attained abortions and left with contraceptive methods. Even 17 years since that change in legal status, some 30 percent of the women who visit Planned Parenthood clinics believing they are pregnant discover they are not.[5] A service that cannot respond to a woman who is currently pregnant or believes she is pregnant neglects a troubled and very needy group of women and loses an important case-finding approach.

The Bangladesh Women's Health Coalition (BWHC) is representative of a very small group of comprehensive reproductive health services for women in Third World countries. In Bangladesh, it is estimated that 780,000 induced abortions are attempted every year by women desperate to prevent another birth. Perhaps 1 percent (7,800) may die from these unsafe, unsanitary procedures. This amounts to one-fourth to one-third of all women who die from pregnancy and childbirth in Bangladesh (Germain, 1988). In 1976, the government of Bangladesh began to endorse and directly provide "menstrual regulation" services through government health and family planning programs, as a means of ensuring that a woman at risk of pregnancy is not actually pregnant. Dixon-Mueller (1988) outlines three reasons rooted in women's health concepts that argue for the provision of such services. First, menstrual regulation is consistent with women's traditional beliefs and practices, including the use of herbal medicines for "bringing down the period" or washing out the uterus. These are viewed as necessary to maintain good reproductive health. Second, consonant with the first, this method of fertility control is more natural and easily understood than modern mechanisms such as the intrauterine device, oral contraceptives, injections, and sterilization. Third, menstrual regulation is a back-up to contraceptive failure that can result from misinformation about other methods and inexperience in their use. We might add a fourth: Menstrual regulation and other forms of early abortion are very safe and, in some circumstances, for some women, pregnancy termination following contraceptive failure is safer than using oral contraceptives or intrauterine devices.

The Bangladesh Women's Health Coalition is the only nongovernmental organization in Bangladesh currently providing these services. BWHC offers a range of contraceptive services, menstrual regulation, referral for sterilization, and, in addition, treatment of women and children for primary illnesses like dysentery, scabies, upper respiratory tract infections, eye infections, and anemia. Immunizations against childhood diseases are also provided.

The services of the six BWHC clinics are of uncommonly high quality, are reasonably priced for their clients, and, even taking into consideration the subsidy provided, are less costly per unit of fertility control rendered than the government program (Kay, 1988). Though menstrual regulation is a vital part of the BWHC's services and the initial one offered in some of its six clinics, it is not the one in most demand. Menstrual regulation comprises not more than 10 percent of services in any location. In addition, the balance of maternal–child health, contraceptive menstrual regulation, and other services offered by each clinic is highly varied and responds to client demand. The urban centers tend to provide more specialized reproductive health care and less child care, and the rural clinics tend to offer more child care. Yet, in a month each center provides between 80 and 100 menstrual regulation procedures. A very high proportion of these clients (90 percent) leave with a contraceptive method. (This is consistent with findings from other Third World clinics that incorporate menstrual regulation, where 75 percent or more of clients accept a method post-procedure; see Germain, 1988). Because the criteria for menstrual regulation are restrictive (less than 10 weeks must have passed since the woman's last menstrual period), a woman who does not qualify is offered prenatal care. Following delivery, she is eligible for contraceptive and child health services.

This summary of the Coalition's comprehensive approach does not do justice to the richness of the program. However, it is an example of the naturalness with which pregnancy termination—or "assurance of nonpregnancy," as it is called—can be integrated with contraceptive care as well as other reproductive and child health care services.

Conclusion

Though a woman's needs over the course of her lifetime are biologically as well as psychologically integrated, for the most part, services segment these needs, sometimes in an extreme and detrimental way. A pregnant woman may not receive information about contraception or pregnancy termination. A recently delivered mother is urged to accept contraception when she is psychologically focused on the health of the infant, physically exhausted from delivery, anovulatory, and not likely to be sexually active for six weeks postpartum. A fully lactating woman seeking contraception several months postpartum is denied the service because it is believed she might have been exposed to pregnancy and her menses have not resumed. A sexually active adolescent is denied contraceptive information because she is a minor and only becomes a social senior by experiencing pregnancy and/or marriage, forced or not. Contradictions abound in our programming approach. The appropriate constellation of services is one that responds to clients' rhythms and health concepts, rather than inflexible medical demarcations of where a "need" begins and where it ends.

Practical Applications of the Framework

The framework discussed in this paper is a starting point, meant to provoke questions. This section proposes ways in which the framework might be used as a practical and analytic tool.

On no account should the framework be used in any rigid manner, and, accordingly, little attempt has been made to establish a balance between the six interconnected elements. "Choice" is the first element listed because it is so fundamental; a choice of methods is a virtual precondition for achieving quality of care. Beyond this, however, each program may choose to give different emphases to other elements depending upon the maturity of the program, its political history, and so forth. In a recent exercise with trainees of a Johns Hopkins University short-term training program for family planning program managers, participants were asked which of the six elements they felt needed attention in their settings. The majority felt that "information given to users" and "follow-up and continuity mechanisms" were the most neglected areas. This group was drawn predominantly from Africa. Another group, or those representing other regions, might have other priorities.

Though the framework seeks to cover most aspects of care, it still may not be comprehensive enough for all purposes. For example, the International Planned Parenthood Federation/Western Hemisphere Region, Inc. has created its own framework drawing on these six elements, but supplementing them with points vital to its own specific operations. One of the most obvious limitations of the model presented here is that it does not directly deal with issues of access except insofar as choice assumes access (a point discussed in the introduction).

In discussions with managers to date, it has been necessary to "locate" observations regarding the ways in which care can be: (1) described, and/or (2) improved. Issues easily overlap in discussion. Therefore, four major questions for service providers that need to be answered are now laid out:

- —What is the standard of care you wish to offer?
- —Have you prepared adequately to offer a (given) standard?
- —Are clients receiving the quality of care intended?
- —What is the impact of the care given?

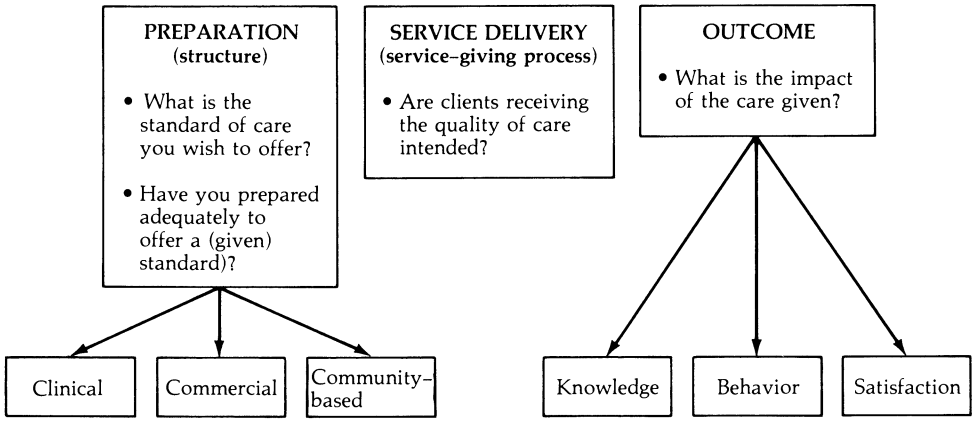
Donabedian (1988) again provides some guidance for mapping these concerns. Though his nomenclature is somewhat different from my own preferred nomenclature, he locates quality issues in structure, process, or outcome. In Figure 2, the six elements discussed in the present framework are listed in the note, and across the top are three different observation points.

Preparation

In the "Preparation" column, which Donabedian might call "structure," the first two questions (listed above) are addressed. These questions should be answered from the perspective of the six elements. Without detailing the steps necessary, the process might include a review of whether, for example, the facility or program is well equipped, whether the staff have been trained in both technical and interpersonal dimensions of care, whether the information used by the program in setting norms is accurate and appropriate, whether supplies and other aspects of logistics are well prepared, and so on. Some frequently overlooked questions that could be asked in this inventory are whether the information imparted in training has been absorbed by workers (Foreit and Leon, forthcoming) and whether they have achieved some level of competence. Assessments to be conducted by management (or outsiders, donors, and others), which look at program effort, would be located at this first "preparation" point.

The preparation required to offer clinical, commercial, or community-based services will differ, and so these three subcategories are illustrated in the first column, too. Background policy factors such as the stated rationale for making family planning services legal and available, overall resource allocations to the public sector, and support for choice of methods through import and pricing mechanisms could also be included here as defining to some extent the implicit standards of care and the quality of the care delivered.

Figure 2 Quality issues to be addressed in family planning programs at the points of preparation, service delivery, and outcome



Note: The "preparation" and "service delivery" questions should be asked with reference to the six elements: choice, information to users, technical competence, interpersonal relations, follow-up mechanisms, and constellation of services.

Service Delivery

The second column, "service delivery," is the logical next step after "preparation" (called "process" by Donabedian). Relatively few studies of family planning care look at the *process* of service-giving. Having prepared the program structure to provide care of a specified quality, what actually happens? Viewing service-giving is difficult because it encompasses so much; establishing a neutral point of observation is almost impossible, and some considerable thought needs to be given to the ends achieved by invading the care-giving process for monitoring or research purposes. Yet, viewing the client/provider transaction is essential. Indirect observation can be made by interviewing both providers and clients, after services have been provided, as to their memory of their interaction. More direct techniques include tape recording, videotaping, and observation by monitors. This sort of research can be used to determine whether all the preparation to provide choice, present accurate information, competently observe technical protocols, relate sympathetically to clients, give follow-up messages, and so forth are handled according to program norms. (See Nessa and Hurell, 1985, for example.) The service transaction reveals in condensed form the immediate outcome of all the preparation. Simmons and others view the client/provider transaction as the appropriate end-point of family planning program management. Indicators of the adequacy of the transactions will be considerably more difficult to derive than those at the programmatic or structural level. Indicators of the adequacy of preparation can flow from policy and centralized norms. However, judgments about the adequacy of service-giving, especially its interpersonal dimensions, are more qualitative. A range of client transactions will have to be observed, as different clients have different needs. For example, whereas denial of a person's choice may be observed in a single encounter, numerous observations will be necessary to see a pattern of limiting choice.

These observations of care-giving are also vital to learn what is actually demanded of workers in the service process. Very often, workers make heroic efforts to meet clients' needs, but these are activities for which they are neither trained nor rewarded. The reverse can also be true—workers are prepared and fielded with a norm in mind, which they apparently willfully ignore. The mission of observation is not punitive, it is practical. Viewing the service-giving process can help managers know whether the tasks established for their workers are achievable and match the demands made upon them by clients.

Outcomes

Finally, the third column in Figure 2 represents outcomes. Within this vertical dimension, three encompassing subjects—clients' knowledge, behavior, and satisfaction—could possibly be viewed along a timeline. Nearer-term outcomes could include clients' knowledgable use of their method, knowledge of alternatives (including sources), and clients' willingness to return to the provider or to refer others. Longer-term client-based indicators of the quality of care delivered could include clients' use-effectiveness (at 12 months) with self-employed methods, or clients' ability over time (for example, 24 months) to manage their own fertility through continuous use of one method or through switching. Ultimately, the longest-term objective would be clients' ability to attain their own stated wishes regarding regulation of their fertility—the wanted or unwanted status of pregnancies in the period after first service contact.

Program managers' interest in outcomes may go beyond these outcome indicators. To date, probing large-scale research on client outcomes has not been undertaken. Some questions have been asked in the World Fertility Survey and in the Demographic and Health Surveys. These have tended to look for broad indications of both access and satisfaction with services. Often, the questions posed are at a general level and elicit courtesy responses. Both these factors may result in generally positive, but not necessarily meaningful, results. When the questions are pared down into more specific areas (which can be organized by the elements)—for example, "Apart from the method you selected, were you given information on other methods? If yes, which ones?"—more realistic answers may be given. At issue here is how soon after the service experience the question is asked, whether questions are refined enough to elicit realistic and meaningful answers, and finally, whether scales are provided so that users' answers reflect an accurate view of their feelings. For example, Huntington (1988) is searching for ways to go beyond the discriminatory power of scales, using verbal cues such as exclamations, and some nonverbal ones such as gestures, as well.

Evaluating the Elements

Though the bias of some analysts may be to separate out observation of the six elements across the continuum presented in Figure 2 (for example, studying choice at the level of preparation, and interpersonal relations at the level of service delivery), my own bias would be to consider each of the six elements as observable (with different indicators) at each of these three points. With regard to choice, for example, an indicator under "preparation" would be the existence of provider norms, availability of supplies, and training staff to offer a balanced choice. At the "service delivery" stage, direct reports or observations of transactions could reveal whether people were being given sufficient information to make voluntary and informed decisions and whether they had access to the necessary supplies at affordable cost. Under "outcome," a mixture of information derived from questions to individual clients (for example, "Were you offered a choice of methods?" or "Were you offered information on a variety of methods?") and program-level indicators (for example, the distribution of method choice by clients' age, parity, and reproductive intention) could be used.

This framework may be used by those who are beginning to design their service system and develop their program norms. For example, at the Planned Parenthood Association of Zambia's family planning center, the staff determined their service-giving goals using the six elements. They separated outcomes desired for clients from those they wished for the program. "Client-oriented key results" included:

- —Clients receive information, education, communication, and counseling services that help them to plan their families and reproductive lives, identify and manage side effects, and know what services the clinic can provide.
- —Clients receive competent care. They don't become pregnant accidentally and don't get sick. They receive consistent, supportive, appropriate management of side effects and complications.
- —Clients receive care, at a visit and over the course of a year, with an appropriate and a minimal expenditure of their time.
- —Clients receive prompt and appropriate care from external agencies.

This example demonstrates that *programs can and should be explicit about their quality goals.* As no one standard of desired quality exists, a given program in the pursuit of "acceptable" quality in their context may decide to take a shortcut with one dimension or another. Resource limits may dictate choices. Managers need to be explicit about what decisions have been made, and why.

A well-established program could presumably use the six elements in this framework to begin the process of engaging staff in discussing the current level of care. In such an exercise, each of the six elements could be used as a discussion topic with managers and direct service-giving staff, using these providers' views initially to pinpoint difficulties. In all cases, however, this information is necessarily supplemented by feedback from clients.

Finally, the framework may have research purposes. As acknowledged earlier, it is unlikely that quality of care will receive all the attention it deserves based simply on principles of human rights and welfare. A large number of donors and others in the field continue to desire information about the level of care that correlates with specific types of performance and they may, in the future, seek to know whether improvements in quality of care will translate into an aggregate benefit beyond individuals' satisfaction with services. The desired aggregate will be, for some, higher levels of acceptance and more sustained contraceptive use.

The national director of family planning may wish to understand the role of differences in the quality of services provided as a determinant of performance at the district or program level. This may include a better understanding of the role of differences in quality of services provided (a research project in India under the direction of Visaria and Jain is exploring this issue). Thus, the "outcome" measures of interest in this type of analysis could include both aggregate-level indexes of contraceptive behavior and clients' qualitative assessments of services received.

In general, for quality of care to be a useful research topic, concepts of program effort would need to be expanded to encompass more technical interpersonal elements of care. Kumar et al. (1989) have developed an assessment approach for clinic-centered programs. Using the framework, within each type of program (clinic-based, field-based, community-based, commercially based), slightly different indicators might be developed, at least in column one (preparation), where the service-giving setting is diverse. There may also be some diversity at the level of service delivery. For example, client/provider exchanges are expected to contrast among those in a clinic, between field-worker and client in the community, and between purchasers of contraceptives and commercial distributors. However, in the third column of Figure 2 (outcomes) a convergence of indicators is expected, insofar as the goal of all programs should be fairly similar—that is, providing people with enough information and supplies to manage their fertility with relative safety, effectiveness, and satisfaction.

Acknowledgments

The author would like to express appreciation to the Quality of Care Advisory Committee and especially Ruth Simmons, Deborah Rogow, Ruth Dixon-Mueller, Adrienne Germain, and her colleagues Anrudh Jain, George Brown, and Beverly Winikoff for their comments on an earlier draft. Special gratitude to Mary Ann Castle for her resourceful research assistance, to Alice Tufel Lesser for her editing assistance, and to Virginia Kallianes for her skill in typing and assembling this and earlier drafts.

Notes

A slightly expanded version of this paper was published originally as a Population Council Programs Division Working Paper, No. 1 (May 1989).

1 Ruth Simmons employed Donabedian's approach to quality of care in prefacing a discussion of her work at the second meeting of the Quality of Care Advisory Committee, April 1987.

2 Jim Foreit relayed this report from work he had undertaken in Lima, Peru in 1988.

3 NORPLANT® is the registered trademark of the Population Council for subdermal contraceptive implants.

4 This discussion is drawn from an earlier paper by Bruce (1986).

5 These data are from personal knowledge. I served as Director of Community Studies and Evaluation for Planned Parenthood of New York City in the first two years after the change in the New York State abortion law (1971–73). We regularly calculated the proportion of women seeking abortion services who were not found to be pregnant. According to Alfred Moran, Executive Director of Planned Parenthood of New York City (1966–89), in recent times the proportion of women who seek abortion services but are found not to be pregnant, is 30 percent.

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Exploratory interview topic guide

Dialysis Centre personnel

- Profile of patients attending the centre (Probe: age group, gender, socio economic background including education and employment, illness duration)
- What kind of services are offered at the centre?
  Probe: Dialysis, patient counselling, meeting and psycho education for family members, group therapy or peer education for patients/ family members, Other services such as lab, pharmacy, etc.
- What type of dialysis are conducted? (If more than one, what are the criteria to choose one method to other?)
- How about patient adherence? (regularity with doctor's appointment, dialysis session, other therapy sessions) In people are not adherent, what are the reasons cited by them to miss a session?
- What is the procedure for admission? (referral from other centres, patient walk in, inclusion exclusion criteria)
- What are the major issues discussed by patients here?
- If a patient expresses his inability to pay for dialysis, are there any mechanisms to assist him? (probe: reduction in fees, referral other centres offering free services, exploring other options for subsidies etc?
- What are the major trends with CKD that you have observed over time? (example, increase or decrease in number patients, any patterns with regards to socio economic status, or risk factors)
- What are your views on the services offered here, and in other centres ? What are the key issues you have noticed? (in terms of HR, quality of services offered, fee for services etc)

Interview topic guide – patients

- Illness details- how did CKD get detected? Duration of illness
- Care seeking trajectory- from the detection of CKD till now
- Economic aspects- treatment cost, additional expenses- how treatment costs are managed
- Views on the services offered at different centres- staff attitude and communication, information given by the staff, views on support services etc
- Family/social support available
- Suggestions to improve the services for CKD patients

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

Title and abstract

	Page/line no(s).
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	1

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	1-2
Purpose or research question - Purpose of the study and specific objectives or questions	3

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	3
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	-
Context - Setting/site and salient contextual factors; rationale**	3
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	3
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	4
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	3-4

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	3-4
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	3-4
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	3-4
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	3-4
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	3-4

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	4-10
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	4-10

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	10-11
Limitations - Trustworthiness and limitations of findings	11

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	NA
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	NA

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014 DOI: 10.1097/ACM.0000000000000388

Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-052525.R2
Article Type:	Original research
Date Submitted by the Author:	18-Jan-2022
Complete List of Authors:	Elias, Maya ; University of Antwerp, Department of Sociology Van Damme, Wim; Institute of Tropical Medicine, Public Health Wouters, Edwin; University of Antwerp, Department of Sociology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Health policy, Health services research, Qualitative research
Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Chronic renal failure < NEPHROLOGY

Accessibility and quality of haemodialysis services in an urban setting in South India: a qualitative multi-perspective study

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Word count excluding title page, abstract, Summary box, tables & references: 5048

ABSTRACT

Objective: To explore the accessibility and quality of existing haemodialysis services in an urban setting.

Setting: The study was conducted in Bangalore city, India.

Participants: A total of 28 stakeholders including 2 nephrologists, 7 duty doctors, 13 dialysis technicians and 6 patients on long term haemodialysis selected from twenty dialysis centres in Bangalore city.

Design and methods: Qualitative study using in-depth interviews. A thematic analysis was done using the Availability, Accessibility, Acceptability and Quality Framework of World Health Orgnization (WHO AAAQ) and the Bruce Quality of Care Framework.

Results: The study found several gaps with regards to the access and quality of existing services for End Stage Kidney Disease patients. The charges for dialysis sessions across settings displayed a wide variance. Patients often started dialysis services in private and later shifted to Government and Non-Governmental Organisations-run centres and reduced the number of weekly dialysis sessions due to financial constraints. Most stand-alone dialysis centres did not have the facilities to manage any emergencies. Most centres did not admit patients with hepatitis or HIV. The quality of care in dialysis centres seemed to be variable and most centres were managed solely by dialysis technicians. There were no psycho-social interventions available to the patients irrespective of the settings. Cost-cutting practices such as employing under qualified technicians, reuse of dialysis equipment, and using substandard water for dialysis were common.

Conclusion: The study highlights the need for more financial and personnel investments in ESKD care in India to ensure optimal care for the growing patient population. The study points towards the need for comprehensive management practices, including diet counselling and psychosocial support. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better accessibility and quality of existing services.

KEY WORDS

End Stage Kidney Disease (ESKD), Access, Quality, Haemodialysis

Strengths and limitations of this study

- The study addresses the dearth of knowledge on the accessibility and quality of existing haemodialysis services in a lower middle-income urban setting.

- The study offers a comprehensive perspective on dialysis care by including multiple stakeholders' perspectives.
- Our study demonstrates the applicability of Bruce's Quality of Care Framework to dialysis care.
- Patients undergoing dialysis services from the private sector could not be included in the study sample.
- We included patients undergoing long-term dialysis, who represent a small subset of ESKD patients; the findings might therefore not necessarily be generalizable to the whole spectrum of ESKD care.

INTRODUCTION

Chronic kidney disease (CKD) has emerged as a major public health challenge worldwide. With a global prevalence of 13.5%(1), it is estimated that approximately 500 million people suffer from CKD, of which 80% live in Low and Middle Income Countries (LMIC)(2). Most LMICs are not equipped to deal with the high burden of CKD; it is often detected at an advanced stage due to the lack of screening programmes, and poor awareness(2),(3). In India, population-based surveys conducted among adults have reported a high prevalence of CKD(4). The Global Burden of Disease Study (2017) reported that there are more than 115 million people with CKD in India(5). CKD can be a complication of many diseases: the most commonly reported risk factors for CKD in India are hypertension and diabetes(6),(7),(8).

The progression of CKD is usually slow(9), but when the patient reaches the most advanced stage of illness, i.e. end-stage kidney disease (ESKD), the kidney functioning is damaged to the extent that the patient needs a renal replacement therapy (RRT), an artificial process used to remove water, electrolytes and waste substances from the blood. Haemodialysis is the most commonly used RRT in India(10). The other options are kidney transplant and peritoneal dialysis, but these are rarely used in the country(11),(12). Haemodialysis uses an artificial kidney (haemodialyzer) to remove waste and extra fluid from the blood. The filtered blood is then returned to the body with the help of a dialysis machine.

Once the patient is advised to undergo haemodialysis, a central venous catheter or an arteriovenous fistula is created as an entry point for haemodialysis. To insert the central venous catheter, a small incision is made in the skin over the selected vein located in the neck, upper chest, or groin. The fistula is created between two blood vessels in the patient's arm through a small surgical procedure. In India, most patients undergo emergency haemodialysis(13), wherein a line access using a catheter is created and later patients are advised to switch to the arteriovenous fistula. Haemodialysis sessions usually last three to five hours. As per the Indian Society of Nephrology guidelines, a patient with ESKD is advised to undergo haemodialysis sessions three times a week(14). Along with dialysis, patients need medication and supplements and may require blood transfusions. They need to undergo regular laboratory examinations to check for common infections. ESKD patients on dialysis are prone to infections, due to their acquired immune deficiency status, frequent hospital admissions and blood transfusions(15). There is a chance of 'machine to patient infection' of blood borne diseases such as hepatitis and HIV during haemodialysis. In India, Hepatitis C Virus infections among patients who undergo dialysis are reported to be high, and infection is a key cause of mortality among dialysis patients(16).

Apart from premature mortality, ESKD is also associated with loss of productivity and high financial burden. In India, facilities that offer haemodialysis in the public sector are limited to tertiary care hospitals situated in district headquarters or cities. Due to this, patients have to depend heavily on the private sector for haemodialysis and other support services, which often results in huge out-of-pocket payments for patients and families(17),(18). Patients with ESKD often require emergency admission to hospital for dialysis, which further adds to their financial burden. The charges for a haemodialysis session in India vary from US $13- 40 (INR* 1000-3000) with additional monthly charges for medicines of about US$ 65-70 (INR 5000)(19). It has been reported that due to financial constraints, only 10% of end-stage kidney disease patients in India receive any renal replacement therapy and of those, >70% die within the first 3 months due to inadequate financial resources to continue therapy(20),(21).

While ESKD poses a huge economic burden to patients and families, it also poses significant challenges to health systems(22),(23). Many developed nations spend more than 2–3% of their annual health-care budget for the approximately 0.02-0.03% of patients with ESKD (24). Considering the magnitude of ESKD and the financial constraints on patients, the Government of India introduced the Pradhan Mantri National Dialysis Programme in 2016, in which it announced establishing at least one dialysis unit with eight machines in each district to offer free haemodialysis to people living below the poverty line(25). However, India still has less than 2000 nephrologists(26),(10), and 4950 dialysis centres†, of which 80% operate in the private sector. It is estimated that a centre with ten haemodialysis machines operating three shifts per day can only cater to 60 patients per week. This is inadequate to meet the existing

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* INR stands for Indian Rupee. One USD is approximately INR 70.

† https://www.expresshealthcare.in/features/breaking-barriers-to-dialysis/277182/

demand for services.

The research on ESKD in India has largely focussed on its prevalence, risk factors and treatment costs(5), (6),(19). There is however a clear knowledge gap regarding the ESKD care process in India: the access to and quality of services offered. This requires in-depth qualitative research complementing the quantitative studies cited. The qualitative studies conducted on ESKD have so far been limited to either single centre experiences or solo perspectives from patients or providers. This qualitative study tries to address this research gap by explicitly exploring the access to and quality of ESKD care using multiple stakeholder perspectives, in an urban setting in South India.

METHODS

Study Design

With the objective of producing in-depth knowledge on the accessibility and quality of dialysis care in India, a qualitative research design (using thematic analysis) was employed for the study.

Study setting

The study was conducted in Bangalore, the capital city of Karnataka State in South India. Bangalore city is part of Bangalore Urban district, which has an area of 2196 sq. kms and a population of over 9 million(27). The region has 104 Primary Health Centres and seven General Hospitals in the Government sector and more than 300 hospitals/nursing homes in the private sector. Bangalore is known for the presence of corporate hospital chains, managed by both national and international players.

Sampling and Data collection

Before the primary data collection, a preliminary mapping of dialysis centres was done by a desktop search, which yielded a result of 88 dialysis centres. From this list, the centres were categorised into three types based on the type of ownership: Private, Government-run and centres run by charitable institutions or Non-Governmental Organisations (NGOs). To get a good representation of each of these settings, twenty centres were selected purposively for the study, of which 14 were in the private sector, 3 in the Government sector and 3 were run by charitable trusts. Basic details of the dialysis centres were captured using a checklist (details captured attached as supplementary file 1). From these centres, interviews were conducted with a purposively selected consenting sample of patients, dialysis unit technicians, duty doctors, and nephrologists to ensure maximal representation of different stakeholders. These interviews were aimed at capturing their perspectives on the dialysis services including accessibility and quality-related issues. A semi-structured interview schedule based on the World Health Organisation's Availability, Accessibility, Acceptability and Quality (AAAQ) framework (supplementary file 2)(28) and Bruce's Quality of Care framework (supplementary file 3)(29) was used to capture the different aspects of accessibility and quality of dialysis services by different stakeholders. These interviews were conducted between September to December 2020 by the first author, who is an experienced qualitative researcher. Each interview took 45 to 60 mins (interview topic guide attached as supplementary file 4). The interviews were conducted in the native spoken language Kannada and were later transcribed to English. Table 1 shows the number of participants interviewed in each category.

Table 1: Details of participants interviewed‡

Participant category	**Type of dialysis facility**			**Total**
	Private	**Government**	**NGO**	
Nephrologists	2	-	-	2
Duty doctors§	1	3	3	7
Dialysis technicians	8	3	2	13
Dialysis patients	-	3	3	6
Total				**28**

Data analysis

A thematic analysis was done, using Nvivo (12) qualitative data management software (30). The interview transcripts were imported to Nvivo for coding. After the coding, they were categorised into different themes and subsequently these themes were examined and organised into different components of the WHO AAAQ framework. The quality of care was further categorised as per the Bruce Quality of Care framework. This framework identifies six dimensions of Quality of Care – choice of methods, technical competence, information given to clients, interpersonal relations, mechanisms to ensure follow-up and continuity, and the appropriate constellation of services.

Ethics

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‡ The Government and NGO run dialysis centres did not have any nephrologists present at the time of visit

§ A medical officer on duty, who is an MBBS graduate. The National Dialysis programme stipulates the presence of one duty doctor for ten patients.

The study protocol was approved by the Ethics Committee for the Social Sciences and Humanities EA SHW- of the University of Antwerp, Belgium (Ref No: SHW_18_82) and permission was taken from the centre authorities before the interviews. Informed consent was taken from the participants. Confidentiality was maintained, all identifying details were removed from the interview transcripts. Authors adhered to the Standards for Reporting Qualitative Research (SRQR), throughout the course of the study (31).

Patient and Public Involvement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Availability of dialysis services

Most dialysis centres visited were founded in the last 3-6 years. The Government-run dialysis centres were attached to general hospitals and run on Public Private Partnership model, where the facility was located inside Government hospital, but the management was by a third-party agency. While both government and private dialysis centres had 2 to 10 machines, NGO run centres had up to 40 dialysis machines. Most of them work 3 shifts/day and were open six days a week (which at maximum capacity equals 18 dialysis treatment sessions per week, supporting a 3x per week prescription for up to 6 patients). The common services included haemodialysis, and supply of medicines and other nutritional supplements. Only three private centres had dietician services available. Since the Government centres were located inside a hospital, patients could get the blood examinations done at the same hospital's laboratories. Six private dialysis centres which were attached to bigger hospitals had laboratory facilities in the premises. The centres, irrespective of the settings were mostly managed by dialysis technicians and nursing staff. Duty doctors were present in seven private centres, two Government centres and one NGO centre. Only two private centres had nephrologists at the time of visit. Other centres reported that they have a visiting nephrologist, who is 'on call'.

Accessibility of dialysis services

Physical accessibility

All dialysis centres catered to patients coming from a distance of 20-40 km. In the centres run by charitable institutions, a few patients were coming from the nearby districts travelling 3-4 hours for each dialysis session. All centres in the Government and NGO sector were run at full capacity. Technicians across settings reported of increase in patient numbers over the years. Technicians from four dialysis centres in private sector and 2 centres in NGO sector reported starting additional shifts in the last two years. A senior technician from a private centre observed:

> *In 1999, we had two dialysis machines and we used to do two shifts, now we have to do daily 4 emergency dialysis, apart from managing the regular patients. Patient numbers have increased, it has become common like a fever. Now we have about 8 machines, and all the machines are occupied, except for the late-night session. (Technician_Private)*

> *Stand-alone centres do three shifts usually while centres that are part of larger chains such as [centre name], have started night shifts too. The Government-run centres usually do not have enough manpower and other supplies to run extra shifts. (Nephrologist_Private)*

While the private centres had both short term and long-term patients, the Government and NGO run centres reported to have a fixed set of clientele, with most patients coming from the inception of the centre or for a period of 3- 4 years. Only when an existing patient died or moved to another centre, a new admission took place. While the private centres received occasional enquiries of new patients, all Government and NGO-run centres visited had more than ten patients waiting to be enrolled, and the waiting period was approximately three to six months. When there was a vacancy, patients coming with staff or local political leaders' recommendations were given priority for admission.

***Non-discrimination (accessibility for all patients*)**

Only three centres provided dialysis for patients with Hepatitis B, Hepatitis C or HIV, commonly referred to by the staff as 'positive patients.' All the centres, irrespective of the setting, insisted on a blood test for these three conditions as a prerequisite for admission and if the result was positive, most centres denied admission. According to the staff, it is mainly due to the lack of infrastructure, human resources, and cost concerns. The centres catering to patients with these conditions kept one to two machines exclusively for them and allotted a technician exclusive to this section. For such patients, dialyser and other accessories were for single use. For small centres, this is not cost effective, so they did not admit any positive patients.

> *There should be a separate setup for Hepatitis C, B and HIV positive patients. We cannot have the same machines. We have done a separate setup for this, but right now we are not doing it because for positive cases, the cost is double. (Duty doctor_NGO)*

> *We don't admit seropositive [hepatis B and C, HIV] cases here. Not many positive cases come here. We want to make optimum use of the machines, so we don't take them.(Nephrologist_private)*

The stand-alone dialysis centres did not have the capacity to take care of emergencies, so they didn't admit patients with comorbid heart or lung-related conditions or other complications. Patients who needed emergency care had to depend on higher-level centres.

Economical accessibility (affordability)

All the patients interviewed were from lower to lower-middle socioeconomic status and were availing dialysis services from Government and NGO-run centres. All of them were long term dialysis patients undergoing dialysis for the last 3-10 years and reported having started their dialysis sessions from private centres and later shifting to either NGO/Government- run centres due to financial constraints. Only one patient was working as an auto driver, all others depended on family members for financial support. Three patients reported that they were employed before they were diagnosed with ESKD, and they had to leave their jobs due to the illness symptoms and repeated hospitalisations. None of them had any insurance coverage.

In private centres visited, the out-of-pocket expenditure per dialysis session varied between US$ 11.4 to 42.8* (INR 800 to INR 3000). Government and NGO-run centres offered subsidised care; the average cost borne by patients per dialysis session was US$ 5.7-7.1 (INR 400-500) excluding the charges for blood investigations and medications. The technicians reported that approximately 30-40% of their patients had severe anaemia and required additional injections or blood transfusion. They reported that on average, monthly blood investigations would cost US$ 50- 71.4 (INR 3500-5000) in private centres, and US$ 14.2-21.4 (INR 1000-1500) in charitable centres. Patients with other common comorbid conditions would pay about US$ 500 (INR 35,000) in private centres and about US$ 142.8-171.4 (INR 10,000 to INR 12,000) in Government and NGO- run centres per month. Due to financial constraints, patients often skipped dialysis sessions or shifted from private dialysis centres to either Government or NGO facilities. In the long run, patients often reduced the weekly dialysis sessions and frequency of blood examinations.

> *I am not able to earn for the last ten years, I had to use all my savings for the treatment, I have spent about 18 Lakhs [US$25,000] so far. I have to pay rent. My wife was not working. After I became a patient, she started going to nearby houses as a domestic*

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* INR to USD calculated at the conversion rate of 70.

> *help. I started coming here now because I don't have money to go to private. (Patient_Government)*

> *We try to do 3 dialyses[per week] for everyone. But if they cannot bear the cost, then they do 2 dialyses. They do this to save 300-400 rupees a week, but if they get into any complication [because they skipped dialysis], then they will end up spending 30 to 40 thousand rupees to manage that. (Duty Doctor_Private)*

Quality of care

The key findings related to quality of dialysis services are organised below, using the six dimensions stipulated in the Bruce quality of care framework.

Choice of methods

Haemodialysis was the only renal replacement therapy provided, except for one private centre which offered kidney transplants. None of the visited centres provided Peritoneal Dialysis (PD). The technicians shared that though they have learned about PD and its advantages, they never practised it. According to them, in the Indian context, it is difficult for patients to opt for PD because the surroundings need to be kept sterile and clean and most patients do not have enough resources for that. None of the interviewed patients was given PD as a treatment option and they were not aware of the PD process. None of them had registered for renal transplant.

> *I have spoken to doctors abroad. There they prefer Peritoneal Dialysis. Here we don't do it because patients can't afford to have a separate room for it, also the fluid they use is very expensive., It could be because only a few people are using it. (Technician_NGO)*

> *PD has to be done 24/7, and here it is not very practical. Also you need the presence of someone to assist. Patient housing and other conditions are not very suitable for PD in our setting. So, PD is slowly going out of practice here (Nephrologist, private)*

Information given to clients

Patients reported that they did not have any prior knowledge of ESKD, its symptoms or management before they were diagnosed. All of them were caught unawares of kidney failure as a complication of diabetes or hypertension and were subsequently advised to undergo haemodialysis. Nephrologists and technicians reported that most patients came with kidney failure because of undetected hypertension or diabetes. Patients reported that they learned about the complications of dialysis, diet, and weight management over the years, and tried to manage complications at home to the extent possible.

> *I had BP [Hypertension]. I was not taking medicine. I neglected. I didn't know it will lead to this type of problem [kidney disease]. (Patient_NGO)*

> *Most patients will present with symptoms of renal failure, and when we do the examinations, many will have uncontrolled diabetes or hypertension. When we ask the patients why they did not take medicines, they say we did not know. (Nephrologist, private)*

Interpersonal relations

All dialysis centres provided dialysis in open wards, with beds next to each other. Since most patients had fixed days and timing for dialysis, they saw and interacted with the same set of fellow patients. Patients shared their experiences and learned from their peers about managing the symptoms. A duty doctor in a Govt centre observed that having open wards helped in reducing patient anxiety regarding the dialysis process.

> *I think open wards are good. Even screens between patients are not necessary. If there is a screen and we are attending a patient [with complication], other patients think we are doing something to the patient and start worrying. If it is open, then they can see openly what we are doing and what we are saying. They will know there is nothing serious.*(Duty doctor_NGO)

A nephrologist observed that in Government and NGO-run centres, patients had more opportunities to interact with other patients. In Private centres, most patients would arrive at their fixed timing for the dialysis and their interactions are usually limited to the staff and at most the patients who occupy the next bed.

Mechanisms to ensure follow-up and continuity

Technicians and duty doctors from the NGO-run centres reported that patients regularly attended their scheduled dialysis sessions since it was free or subsidised. Patients were advised not to travel for more than two days. When patients had to travel to far-off places or for longer duration, either they must skip a scheduled dialysis, or they must enrol in a local dialysis centre. Staff shared that this is a common reason for infections.

> *Some patients travel to their hometown or relatives houses for festivals or family functions. If they go for more than two days, they have to get the dialysis done and will go to some local place and get it done. Once they come back and we do the blood test, we find that they have become positive for Hepatitis B or C.*
> *(Techinician_Private).*

All centres maintained patient records. A few centres had detailed case notes including previous treatment details, lab reports, and other clinical parameters while others kept only patient contact details along with the blood pressure readings and weight on the day of dialysis.

Appropriate constellation of services

The dialysis centres in the private sector had better infrastructure, separate beds and screens or curtains between the beds. Govt and NGO centres provided the services in open wards, with beds next to each other. There was no separation between male and female wards in most of the centres. From the dialysis centres visited, three centres in the private sector had a dietician who provided diet counselling to the newly admitted patients. Patients undergoing dialysis under Government centres, where the medicines are supplied free of cost, often faced a shortage of required medicines and supplements. Due to this, they had to spend money on purchasing medicines from private pharmacies.

> *Because medicines were not available, many times I have gone to other places to get it. Even last month I had gone to another centre. We complained to the Medical Officer last month and after that, there is no problem."(Patient_Government)*

While it was noted that patients often felt helpless and hopeless thinking about the treatment expenses and the prognosis of their illness, none of the visited dialysis centres had any counsellors or social workers offering counselling or any other psychosocial support to patients.

> *All your money will all be spent [for the treatment]. If you go inside the ICU once, you will need a minimum of 50000 rupees. It has been very difficult for me; I have even thought of committing suicide. What else can be done? (Patient_NGO)*
>
> *I have not seen a counsellor in any dialysis centre. In India, we don't have the concept of a counsellor. Only the doctors talk to the patients. There is an issue of time constraint. We may not have enough time to talk to everyone. (Nephrologist, private)*

Technical competence

All the visited centres, irrespective of the sectors, were mainly managed by dialysis technicians. Seven centres had duty doctors, only two centres had full time nephrologists. In all visited centres, one or two technicians managed the centres with 7-10 patients in a single shift. They reported that there are 6 months to one-year dialysis technician courses available and such courses do not equip the technicians to notice complications during dialysis.

> *In many centres there are no nephrologists, and there are unqualified technicians. They may not even know how to read and write properly, but they will be doing dialysis. They just know how to switch the machine on and off, nothing else. (Nephrologist_private)*

Private dialysis centres have less qualified technicians to cut costs. They may not practice safety precautions while handling of the dialyzer and other equipments which would lead to infections and other complications. Patients won't know what is happening.(Technician_Government)

Due to human resource crunch, the same technicians handle patients with and without infections such as Hepatitis and HIV. This coupled with their lack of adequate training puts patients at risk of infections. Other cost cutting practices reported were the use of lower quality water purifiers, and other equipment including dialysers and tubes. These practices led to patients getting infections and having other complications during dialysis. All centres used the dialyser for ten dialysis sessions for a patient and all three centres in Government reused the tubes as well. The technicians shared that if the machine parts were not cleaned with strict safety precautions, 'machine to patient infections' could happen. Technicians and duty doctors reported that they commonly saw infections such as Hepatitis C (HCV) and Hepatitis B (HBV) among patients. Staff from a few dialysis centres mentioned that they did not admit patients referred from certain centres due to the fear of transmission.

People with Kidney Disease are prone to get Hepatitis C and many hospitals are spreading it like anything. Some hospitals, I can name them, they are harbouring this and spreading. Patients coming from certain hospitals, we know that they will be positive, we know that their quality of treatment is poor.(Duty doctor_NGO)

The water quality is very important; centres are supposed to have monthly water test to make sure the bacteria and toxic elements are controlled. But it costs about 4000-5000 rupees to do it, so most centres don't do it monthly.(Nephrologist_Private)

DISCUSSION

This study throws light on the landscape of dialysis services offered in an urban setting in South India and poses a few important questions on the accessibility and quality of existing services. While it appears that the availability of haemodialysis services may not be a serious issue, economic access is a major challenge. Although dialysis services are predominantly offered by the private sector, the wide variability in charges for dialysis and support services renders them inaccessible for large groups of patients. Though the centres in the Government and NGO settings charge comparatively less per dialysis session, patients from poorer families still do not have sufficient resources to afford these. Also, such centres are too few in numbers to be able to cater to the rising demand for dialysis services. Our findings showed that due to financial constraints, patients are often forced to skip dialysis sessions. Similar findings were reported earlier by V Jha (2013)(32) and Karopady et al (2013)(33). Another study conducted by Gunjeet Kaur et al (2018) found the prevalence of Catastrophic Health Expenditure (CHE) to be as high as 51% among patients undergoing haemodialysis thrice a week(34).

In India, diabetes and hypertension are the key causative factors for CKD and these conditions make patients prone to complications during dialysis. Earlier studies have reported that hypotension, nausea, and vomiting are commonly reported during dialysis. Our study too showed similar findings(35). While infections, especially HCV and HBV are commonly reported in the CKD population due to frequent dialysis and blood transfusions, the number of centres catering to patients with these conditions are very limited. Patients with any comorbid conditions and other complications need to depend on higher centres with emergency facilities, which are too few, especially in the public sector. Private hospitals can cater to only a subsection of ESKD patients, who can afford their services So, patients end up shuttling between centres in different settings depending on their illness status and paying capacity.

The study findings raise important questions regarding the overall quality of dialysis services across settings. The quality of the dialyser and water used for dialysis are important predictors for better patient outcomes (36). Our study showed that water purifiers are available at varying costs and currently there are no mechanisms to ensure the water quality. Though National guidelines and guidelines issued by the Indian Society of Nephrologists recommend that nephrologists must be part of regular staff in the haemodialysis centres, the centres are managed solely by dialysis technicians and from our respondents' accounts, it appears that the quality of their training is variable. If technicians are capable of identifying the early warning signs, many complications could be averted, including problems with fistula(37).

Though the benefits of peritoneal dialysis is well documented(38), our findings show that it is still not accessible to patients with CKD. Acknowledging this, the Government of India published a set of guidelines for states for starting peritoneal dialysis facilities as part of the Pradhan Mantri National Dialysis Programme(39). It provides the necessary guidance for states to set up peritoneal dialysis centres and serves as a best practice document for providers of peritoneal dialysis, ensuring delivery of high quality, cost effective CAPD services. While it is a welcome move, states will have to implement it in an effective and timely manner.

CKD is known to be associated with various psychological issues such as depression, anxiety, and poor quality of life. A multi-centre study conducted in India found that depression was common among haemodialysis patients and long-term dialysis and poverty status had a significant relationship with depression(40). Another study conducted among CKD patients from Karnataka reported depression to be more common in patients on dialysis compared to other modalities of treatment(41). While supportive interventions have been found to be effective among patients with CKD(42), our findings indicate that existing services do not cater to the psychosocial needs of the patients. Having the services of a trained counsellor or a social worker available in these centres would give the patients an opportunity to discuss their psychosocial problems, which could potentially help in reducing their emotional discomfort during the dialysis process and improve overall treatment outcome. Earlier studies have reported a positive effect of counselling on patients with CKD(43).

Limitations of the study

While the study provides a snapshot of the dialysis services provided in an urban setting in India, it is subject to certain limitations. The study took place in a selection of dialysis care facilities in an urban setting in India and the results might therefore not necessarily be generalizable to other settings. Due to the difficulty in obtaining necessary approvals from the authorities, patients undergoing dialysis services from the private sector could not be included in the study sample. The study respondents were undergoing dialysis for longer term, and we acknowledge that they represent a small subset of CKD patients and the findings apply to this subset of patients and not necessarily the entire spectrum of CKD.

Implications of the study and future directions

By including multiple stakeholders, our study offers a comprehensive perspective on CKD care in a lower middle-income urban setting. It also demonstrates the applicability of Bruce's Quality of Care Framework to ESKD care. The study highlights the need for more financial and personnel investments in ESKD care in India to ensure optimal care for the growing patient population. The study points towards the need for comprehensive management practices, including diet counselling and psychosocial support. While there are comprehensive guidelines on the establishment and management of dialysis services, more policy attention needs to be on effective implementation of these, to ensure better access and quality of existing services. With the increasing burden of CKD in India, more in-depth studies are needed, exploring patient experiences at different stages of their illness, which would help in designing appropriate interventions at each stage of CKD.

Contributorship statement

MAE conceptualised the study, in consultation with WVD and EW. MAE collected the data, conducted the first level of analysis, and prepared the first draft of the manuscript. WVD contributed to the study design, data analysis and writing the manuscript. EW contributed to data analysis and writing the manuscript. All three authors participated in data analysis discussions and revision of the manuscript and concurred on the final draft. All authors met the ICMJE criteria for authorship.

Competing interests

None to be declared

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article

Data sharing statement

Data can be made available on reasonable request

Acknowledgements

We thank Dr. Yashwanth Kumar KY, Assistant Professor, Department of Nephrology, Vydehi Institute Of Medical Sciences And Research Centre, Bangalore for his analytical inputs. We thank Prof Arima Mishra, Azim Premji University, Bangalore for her guidance and support. We acknowledge Dr. Thriveni S Beerenahalli for her help and support for the study.

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Dialysis Centre details	Total number of centres
Type of ownership	
Govt	3
Private (Individual)	8
Private (corporate)	6
NGO/trust	3
No of dialysis machines	
<5	2
6-10	11
11-20	5
>20	2
No of shifts per day	
Two	2
Three	12
Four	4
No of working days per week	
Six days	16
Seven days	4
Total number of Staff (including support staff)	
1-5	2
6-10	10
11-15	4
16-20	4
Other facilities available	
Pharmacy	12
Laboratory	9
Canteen	6
Services provided	
Haemodialysis	20
Peritoneal dialysis	0
Transplant	1
Diet counselling	3
Psychological counselling	0
Home visits	0

AVAILABILITY

Need to have sufficient quantity of functioning public health and health-care facilities, goods and services, and programmes.

- Do you collect data disaggregated by different and multiple stratifiers – such as infant/adolescent/older persons, rural/urban, people with disabilites, ethnic groups, men/women/transgender – on the availability of health facilites, goods, services and programmes for these populations?
- Are you looking at coverage gaps for populations that are not receiving a sufficient quanitity of facilies, goods, services, and programmes?
- Do you monitor the ratio of skilled health workers to the populations needs?

ACCESSIBILITY

Health facilities, goods, and services have to be accessible (physically accessible, affordable, and accessible information) to everyone within the jurisdiction of the State party without discrimination.

- Have you identified barriers to safe physical accessibility to facilites, goods, services, and programmes for different vulnerable or marginalised groups?
- Have you provided norms and standards that seek to overcome barriers to physical accessibility?
- Have you identified financial barriers to services for different vulnerable or marginalised groups?
- Do you monitor the extent to which health-related information is made available at country/district level for different vulnerable or marginalised groups including people with disabilities?
- Do your technical documents provide accurate and understandable information about your health area for all groups?

ACCEPTABILITY

The social and culteral distance between health systems and their users determine acceptability. All health facilities, goods, and services must be respectful of medical ethics and culterally appropriate, sensitive to gender and age. They also need to be designed to respect confidentiality and improve the health status of those concerned.

- Do you ensure that health facilities, goods, services and programmes are people-centred and cater for the specific needs of different populations?
- Are WHO programmes acceptable to diverse groups?
- Do you assure that goods, facilites, services and programmes are realised in accordance with international standards of medical ethics for:
  - confidentiality?
  - informed consent?

QUALITY

Health facilities, goods, and services must be scientifically and medically approved and of good quality.

- Have you established or ensured norms and standards of quality for:
  - health services?
  - health facilities?
  - health professionals?
  - essential medicines and equipment?
  - determinants of health?

Fundamental Elements of the Quality of Care: A Simple Framework

Judith Bruce

This article argues for attention to a neglected dimension of family planning services—their quality. A framework for assessing quality from the client's perspective is offered, consisting of six parts (choice of methods, information given to clients, technical competence, interpersonal relations, follow-up and continuity mechanisms, and the appropriate constellation of services). The literature is reviewed regarding evidence that improvements in these various dimensions of care result in gains at the individual level; an even scarcer body of literature is reviewed for evidence of gains at the level of program efficiency and impact. A concluding section discusses how to make practical use of the framework and distinguishes three vantage points from which to view quality: the structure of the program, the service-giving process itself, and the outcome of care, particularly with respect to individual knowledge, behavior, and satisfaction with services.

(STUDIES IN FAMILY PLANNING 1990; 21, 2: 61–91)

The last decade has seen considerable interest in identifying the critical features that make family planning (FP) services effective in meeting demand. Concurrently, the family planning field has rearticulated its commitment to individuals' and couples' right to make voluntary choices about the number and timing of the children they want, and select compatible means to achieve their goals. Yet, despite intensified concern with program performance and the ethics of family planning service provision, appraisals of family planning programs have generally neglected a central dimension—the quality of care rendered. The time has come to reverse this neglect. Improvements in the quality of services will result in a larger, more committed clientele of satisfied contraceptive users. Over the long term, this expanded base of well-served individuals will translate into higher contraceptive prevalence and, ultimately, reductions in fertility. Within private and commercial programs, where clients provide all or partial cost-recovery, the laws of the marketplace suggest that better services at the right price will attract more patrons. Within publicly supported programs, both clinic and community-based, it is likely that improvements in the quality of services will result in greater initial acceptance and more sustained use.

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Though the value of improved care will differ by setting, universal gains would be expected at the individual level in terms of personal well-being and the ability to regulate one's fertility. Speculating more broadly and in very simplified terms about the societal impacts of improved care, in parts of Asia, it is inadequacies in the array of services, and not simply limited contraceptive supply, that constrain expanded use of contraceptives and, in the long run, further reductions in fertility. In Latin America, contraceptive prevalence is generally high, with the stark exception of some indigenous populations and continuing but declining differentials between urban and rural prevalence. Concern exists in many Latin American and Caribbean countries that substantial misuse of self-employed methods occurs as well as overuse of sterilization, and excessive related unhealthful practices, such as delivery by caesarean section when unnecessary. Thus, in this region, the immediate impact of improving services and increasing effective use of temporary methods may be seen in improved client health rather than in the reduction of fertility, but over time, effects are expected in both. In sub-Saharan Africa, underlying health and cultural factors are complex and institutional capacity is limited. Though it may be tempting to make institutional improvements rapidly, services must be built up carefully, so as to engage the trust and patronage of African women and men in cultures where large numbers of children are still highly desired and uncertainty about and unfamiliarity with modern contraceptives may overpower an emerging and co-existent interest in birth spacing.

Beyond the global hypothesis that improvements in the quality of care are essential from human rights and demographic perspectives, it has been proposed that the largest potential reward for improving services exists where societal demand for child spacing and fertility regulation is low or unsteady—and, as a corollary, where maternal and child health (MCH) is poor. At both ends of the spectrum, whether demand is intense or very limited, improvements in the quality of services may only marginally increase contraceptive prevalence. Individual women who are virtually desperate to control their fertility will tolerate almost any type of care, including accepting methods that are unproven, incompatible with their health, and even life-threatening, such as unsafe abortion procedures. Nineteenth-century Europeans evolved social customs, engaged in specific sexual practices, and employed a high degree of abstinence to achieve fertility decline. On the other hand, for those who wish to have as many children as possible, with no or minimal spacing between pregnancies, an appealing family planning clinic or hospitable fieldworker may make no difference.

However, most societies and most people hold preferences between these extremes. Most do not want all the children they can physiologically produce, even if they hold high fertility goals. Most couples would prefer, if possible, to find an acceptable and safe way to enjoy an active sexual life while successfully avoiding constant pregnancy. In numerous different settings, the availability of services of reasonable quality will be of humane value to the prospective clients and, over time, should assist the achievement of national demographic goals.

Defining Quality

Very few systematic studies are available to guide us in defining and measuring the quality of services, but we do not begin at zero. The extraordinary analysis and documentation of the family planning programs operated by the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B) in Matlab Thana, and its efforts to transfer this knowledge to the regular government program in what are known as the "extension areas," provide an unparalleled picture of the features of a supply system, its management structure, workers' roles, and clients' responses. The recent assessment of family planning effectiveness by the National Academy of Sciences (Lapham and Simmons, 1987) was a masterful synthesis of knowledge about programs and gave a good deal of weight in its analysis to client/provider transactions. Lapham and Mauldin's (1985) review of program effort in 100 countries, though relying upon informants rather than clients, sought to go beyond official enunciations about availability to describe services in more realistic terms.

Analyses of the availability of services (Hermalin and Entwisle, 1985) and the monetary costs of services to clients have necessarily involved considerations of quality. Indeed, these three issues—quality of services, their cost, and availability—are difficult to consider discretely: a choice of methods is not possible without sufficient supply points. The interpersonal dimensions of care are strongly influenced by the quantity of care—the amount and nature of contact between the client and the provider system. The continuity of care provided is similarly influenced by access to supply points and/or staff. Health planners and individuals alike link costs and quality in their decision-making. Health planners' determinations about which improvements in quality to pursue are founded to some extent on considerations of cost. At the individual level, the client's willingness to pay for services may vary with their perceived quality.

Though it is acknowledged that these topics—availability, cost, and quality—are related and indistinctly bounded, the purpose of this article is to draw a box around the phrase "quality of care" and identify its fundamental elements in family planning and related reproductive health programs.

Confusion about the meaning of the word "quality" itself may have inhibited more rapid progress in this area. Quality, by its connotation, implies an intimidating, possibly costly standard. It is not a standard at all, though; rather, it is a property that all programs have (Donabedian, 1980, as cited in Simmons, 1987).[1] Only a judgment can determine whether quality is good or bad, satisfactory or unsatisfactory. The word and its imputed meaning have emerged in *contradictory contexts*: early family planning literature discussed quality largely with regard to clinical operations; this approach neglected the interpersonal dimensions of care and suggested to some that high quality meant technically sophisticated, expensive equipment. Quality has sometimes been counted as synonymous with the availability and/or accessibility of contraceptives. Both quality of care and availability of services are vital determinants of contraceptive use, but studies of availability rarely provide descriptive material on the unit of service clients receive. Quality has also been defined in terms of potential demographic impact; a recent evaluation of a major Asian family planning program included the proportion of women using long-term methods as a measure of quality (Bair et al., 1987).

These conflicting approaches to the definition of quality and the suggestion that it is unmeasurable may have discouraged managers from incorporating quality of care indicators in their management information system (MIS) and evaluation protocols. Managers have been accustomed to measuring quantity of services provided, by type. Donors' evaluation frameworks, the daily mechanism of management, bureaucracies and their own internal reward systems, and the national government's desire to meet targets—whether counted in demographic terms or numbers of services rendered—have all led to a strong bias to evaluate performance based on volume of activities, sometimes calculated from the base (the individual worker) up to program, subnational, and national levels. The quantitative bias is a powerful force with which to contend.

The sources of information, of tools, and of intellectual sustenance in developing measures of quality will not be found in the scientific literature alone. This literature assists us to some extent, but learning the family planning field's experience, much of it transmitted orally or noted in site visit reports, is also vital. Managers, technical specialists, and workers alike have their own folk knowledge about what constitutes good or adequate quality. This knowledge needs to be revived, revalued, and structured. One is often struck by the dichotomous nature of the population field's self-expression. Quantitatively oriented research and evaluation studies give a dry, satisfyingly organized, if partial picture of the supply of services. In contrast, accounts of personal experiences and trip reports have quite another flavor. Some anecdotes convey a world of meaning about the quality of the service received; for instance, when one woman who had purchased her first pills from a pharmacist asked how to take them, she was told, "The way you take all other pills."[2] A family planning evaluator who recently returned from the field described seeing several women lined up on examining tables, with their legs open, as a physician moved among them inserting IUDs in a space less like a medical facility than a "cage." Most professionals in our field are troubled by this insensitivity and incompetence, but no ready means exist for integrating this discomfort into an evaluation framework.

If quality of services is going to rank alongside quantity of services as an indicator of program performance, the "classical" clinical dimensions of quality of care and the subjective interpersonal aspects must be brought together in a simple and generally agreed-upon framework. Donabedian (1980, 1988) has provided a generic foundation for assessing the quality of health services. This present paper, informed by Donabedian's technical/interpersonal model of care, seeks to specify the quality of family planning and related reproductive health care services. The selection of the six elements and the emphasis placed on them reflects not only logic, but the author's view of the field's experience and the tension created when family planning services are caught between two potentially conflicting mandates: promoting the achievement of demographic objectives and meeting individual health and welfare needs. The framework seeks to respond to the common sense and commitment to human welfare that motivated the work in this field in its early stages.

Quality of Care Framework

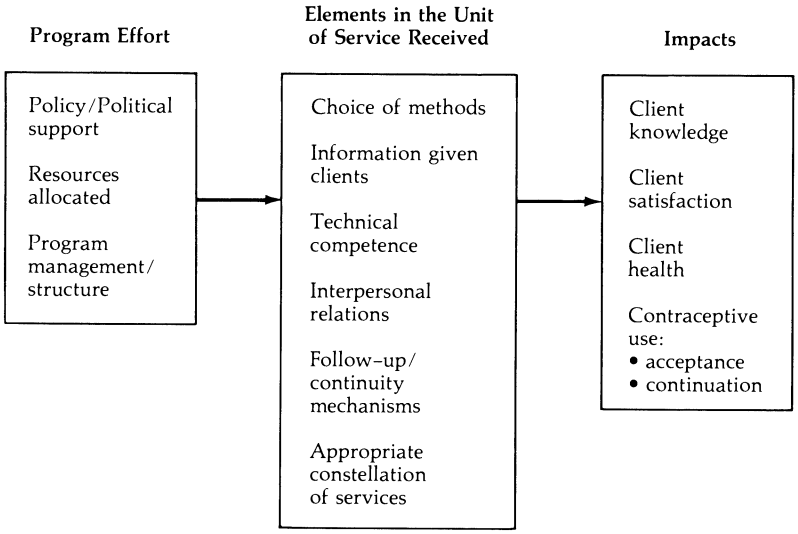
The salient elements of family planning programs that together constitute quality are: choice of methods, information given to users, technical competence, interpersonal relations, follow-up or continuity mechanisms, and appropriate constellation of services. These elements reflect *six aspects of services that clients experience as critical*. This framework is meant to provide an ordered point of departure from which to develop a description of the service unit and define its quality. Though we are concerned with the experience of those who have not successfully connected to services—particularly when their nonuse is attributable to poor availability or negative reports of service—for the moment, our *attention is centered on the experience of those who have gained access to services*. The client usually does not see the apparatus behind her experience, all the vital work required to provide services. Thus, the policies, resource allocation decisions, and management tasks that precede the delivery of services are not directly experienced, but their outcome, the service-giving, is. Figure 1 is a graphic display of the framework and the hypothesized relationships between program effort, quality of the service experience, and its impacts.

The Six Elements

Choice of methods refers both to the number of contraceptive methods offered on a reliable basis and their intrinsic variability. Which methods are offered to serve significant subgroups as defined by age, gender, contraceptive intention, lactation status, health profile, and—where cost of method is a factor—income groups? To what degree will these methods meet current or emerging need (for example, adolescents)? Are there satisfactory choices for those men and women who wish to space, those who wish to limit, those who cannot tolerate hormonal contraceptives, and so forth?

Information given to clients refers to the information

Figure 1 The quality of the service experience—its origins and impacts



imparted during service contact that enables clients to choose and employ contraception with satisfaction and technical competence. It includes: information about the range of methods available, their scientifically documented contraindications, advantages, and disadvantages; screening out unsafe choices for the specific client and providing details on how to use the method *selected*, its possible impacts on sexual practice, and its potential side effects; and finally, an often neglected element, explicit information about what clients can expect from service providers regarding sustained advice, support, supply, and referral to other methods and related services, if needed.

Technical competence involves, principally, factors such as the competence of the clinical technique of providers, the observance of protocols, and meticulous asepsis required to provide clinical methods such as IUDs, implants, and sterilization.

Interpersonal relations are the personal dimensions of service. Relations between providers and clients are strongly influenced by a program's mission and ideology, management style, resource allocation (for example, patient flow in clinical settings), the ratio of workers to clients, and supervisory structure.

Mechanisms to encourage continuity can involve well-informed users managing continuity on their own or formal mechanisms within the program. They can rely upon community media, or on specific follow-up mechanisms, such as forward appointments, or home visits by workers.

Appropriate constellation of services refers to situating family planning services so that they are convenient and acceptable to clients, responding to their natural health concepts, and meeting pressing pre-existing health needs. Services can be appropriately delivered through a vertical infrastructure, or in the context of MCH initiatives, postpartum services, comprehensive reproductive health services, employee health programs, or others.

The six elements of this framework are not utterly discrete. Their quality is interrelated, often determined by common background factors and program policies, operations management styles, and resource limits. Yet, these elements are separable enough that program staff, evaluators, or especially alert clients could develop distinct opinions about each of them. They could also represent points of intervention: methods can be added to the mix, information can be expanded and updated, more appropriate medical protocols can be developed, workers' counseling skills can be improved, follow-up mechanisms can be put in place, and selected services can be added to a program. However, because even incremental change is often difficult to achieve and involves costs in time and money, in the next section research findings and program experience are related that may encourage reviews of service quality. Further, as this framework has practical applications without necessarily heroic efforts, the ways in which health planners, managers, and researchers might use the framework are discussed briefly. A much expanded discussion of its applications, including indicators that could be employed for clinically centered services, is provided by Kumar et al. (1989). In the sections that follow, the impact of each of the six elements in the framework is discussed. In the final section, practical applications of the framework are described.

Choice of Methods

Rationales and Meaning of Choice

It is by now a central principle of family planning programs that a choice of methods should be provided. Providing a choice does not necessarily mean that every program must provide all methods, but the overall program effort on a geographic basis should be sufficient so that prospective users have reasonable if not utterly equal access to a variety of methods.

Over the years, a variety of rationales have been offered to support the proposition that providing a choice of methods is important. Though obvious, it bears repeating that individuals and couples pass through different stages in their reproductive life cycle, and their needs and values change. They may move from wishing to delay childbearing, to space pregnancies, and finally, to terminate childbearing. Many marriages and partnerships dissolve and new ones form, migration leads to spousal separation, and finally, the death of the spouse in midlife is not uncommon. The clinically documented and perceived health risk of specific methods to specific women is a second reason arguing for choice. Despite careful screening for medical contraindications, the process of taking personal and family medical histories from clients does not tell them very much about the possibility of the appearance of unpleasant side effects nor does it necessarily indicate which of these they will be able to manage. A majority of discontinuation of methods in the first year is attributable to side effects. The most comprehensive study (Kreager, 1977) found that in the range of studies of first-year continuation rates, 4–34 percent of IUD acceptors had the devices removed for medical reasons or due to untolerated side effects, and 8–50 percent of pill acceptors discontinued use for the same reasons.

Much about contraceptives has changed in the decade intervening since Kreager's review. For example, the hormonal contraceptives most widely distributed in 1989 have a far lower dosage than their 1970 equivalents, and some contain no estrogen. These biomedical advances are positive from the point of view of women's cardiovascular systems, and have reduced the possibilities of negative health consequences, but they have *not* eliminated side effects. Indeed, some of the lower-dose hormonal methods carry with them a greater probability of extended periods, unpredictable breakthrough bleeding, and other effects of consequence to users. The Dalkon Shield, a dangerous intrauterine device, has been removed from the market, and the newer configurations are long-lasting, easier to insert, and better tolerated by low-parity women. Nonetheless, as with the improved range of hormonal methods (in oral, injectable, and implant formats), users' problems with IUDs are often not predicted through screening but only revealed through use. The increased knowledge about the infection-promoting or inhibiting effects of different contraceptives may intensify the health factor in clients' decisions. Also, women desiring to protect their fertility and health while practicing contraception for possibly decades (from menarche to first birth) may have an increased interest in temporary methods with no known infertility effects.

Thus, switching among methods is common, particularly among first-time and adequately informed contraceptive users. The ability of individuals to switch methods is key to their satisfaction and their ability to practice contraception over a long term. Indeed, observed patterns of contraceptive use make it clear that in industrialized and developing countries alike, first-use segments with temporary methods of contraception are typically under two years. Mauldin's (1978) review of contraceptive continuation rates estimated that (based on data from 33 countries), of 100 women who have an IUD inserted, 34 have it removed before one year, and an additional 10 have it removed in the second year. Of 100 women who have accepted and used oral contraceptives, 55 abandon them before year one, and another 16 discontinue use during the second year. A recent study of contraceptive use among US women indicated that the median use segments of temporary methods was about two years (Grady et al., 1987).

Comparative data from developing countries are more difficult to find. Most studies have been so oriented to looking at the experience of individual (usually clinical) methods that they generally deal only with first-method discontinuation and therefore give no sense of the sequential use of contraceptives by individual users. In developing country settings, there may be fewer methods available to permit switching and fewer cohorts of women who pass through reproductive ages when a meaningful choice of methods was available. If one compares data from the contraceptive prevalence World Fertility Surveys on ever-use and current use, it is clear that many current users are not using the method first selected. Field studies of contraceptive use patterns among specific populations, however, usually verify the assumption that much switching goes on, and some studies have found that switching among methods correlates with long-term use. Data from a household distribution scheme in Bangladesh indicate that two-thirds of those women still practicing contraception 18 months after the initial distribution of methods had switched methods (Bhatia et al., 1980). Philippines data drawn from the national acceptors survey show that 34 percent of the women who were still using contraceptives at the end of 24 months had switched methods at least once (Laing and Alcantara, 1980). In the course of a ten-month study of 200 family planning clients drawn from seven clinics in Botswana, 10 percent switched methods at least once (Stephens, 1978).

There also may be societies where couples' selections are more resistant to change once established. For example, DaVanzo et al. (1987) presented data from Malaysia (1961–75) on contraceptive switching among three different ethnic groups. In general they found an unusual inertia; most women stayed with the same method not simply over time, but from pregnancy to pregnancy. However, they also observed less stability in choice among those who had adopted modern methods. Calculating continuation rates with specific methods between pregnancies they found continuation rates of 73 percent for rhythm, abstinence, and withdrawal; 55 percent for barrier methods; and just over 50 percent for pill use.

Having a choice of methods is both a practical and philosophical commitment to respond to the user's needs. Practically, providers must carefully plan how to provide alternative technologies to clients. Philosophically, the availability of multiple methods reaffirms the program's goal of service to the individual's need for effective contraception, not the promotion of a given method. This orientation to meeting individual requirements as a prerequisite to providing choice in a meaningful fashion bears emphasis. In a now famous set of experiments, a contraceptive program in Bangladesh promoting oral contraceptives with condoms as a second choice was followed by a program that explicitly defined its focus as "client-oriented." This latter program operated in the same area with better-trained workers and seven contraceptive modalities available, resulting in dramatic contrasts in their results, both short-term, as measured through acceptance and continuation, and long-term, as measured through fertility decline (Bhatia et al., 1980; Phillips et al., 1982).

A recent review of the ongoing experience in Matlab and the extension areas with the introduction of new contraceptive methods suggests another vital dimension of providing choice that must be understood. *Real choice is not feasible without an adequately developed delivery system.* Phillips (1988) reviewed the impact of the introduction of depot-medroxy-progesterone acetate (DMPA), an injectable contraceptive. He concluded that, whereas DMPA met the needs of a large clientele and led to a consistent and large layer of use in the Matlab experimental areas, its introduction outside in the extension areas could not be deemed a success. This was not because clients did not welcome its addition, but because the service personnel, visiting pattern, and general intensity of resources were insufficient to deliver DMPA consistently and up to standard. Similarly, the new contraceptive implants, such as NORPLANT®,[3] will become a choice in reality only in contexts where technical competence is assured.

The offering of choice must also recognize the undesirable, but frequent, occurrence of inconsistent supplies. If multiple methods are offered, the likelihood increases that at least one method will be available. Even better, some analysts say, is a program effort in which a variety of methods (both supply and clinical) are available through a variety of sources (Foreit et al., 1978).

Choice and Program Performance

With regard to impact, the role that choice plays in increasing the demographic effectiveness of programs is now well documented. A clear, consistent, and positive relationship exists between the availability of a range of contraceptive methods and contraceptive prevalence rates (Freedman and Berelson, 1976; Mauldin, 1979; Pebley and Brackett, 1982; Potter, 1971; Lapham and Mauldin, 1985). The most recent assessment, and a powerful one, is by Jain (1989), who reviewed the evidence and modeled the relationship between increasing the number of methods available and the demographic impact of programs. Jain lists four central findings from the existing data that indicate the positive demographic impact of method choice. His analysis indicates that:

1 The addition of a method results in a net addition to contraceptive prevalence.
2 One-method family planning programs are inadequate to meet individual fertility goals.
3 Availability of multiple methods improves continuation of use.
4 Contraceptive prevalence depends upon the number of methods available at multiple service points in a country.

Reanalyzing data collected by Lapham and Mauldin (1985), Jain found that a little less than two methods were effectively available per country, and the countries with more methods available had markedly higher contraceptive prevalence. He modeled these relationships and concluded that, "the widespread addition of one method . . . to the choice of methods available in a country would be associated with an increase of about 12 percentage points in the practice of contraception" (Jain, 1989: 11).

Relatively very little research has been done to learn explicitly from users how their perception of a choice of methods is reflected in their sense of satisfaction with the program and their contraceptive use. However, a great deal of indirect evidence demonstrates how a lack of choice affects clients' behavior. In a recent study of oral contraceptive, IUD, and condom acceptors in five Indonesian family planning clinics, clients were asked 18 months after their initial contact whether they had received the methods they requested, whether they were still using contraceptives, and, if not, when they had discontinued. Of those who reported they had not received the method they wanted, 85 percent had discontinued within a year. The comparable rate among those who received the method requested was 25 percent. Whether a client's choice of method was "granted" or "denied" turned out to be more powerful than all other independent variables in explaining the tendency to continue or discontinue use. Regardless of method, women who did not receive their original request had lower continuation rates (Pariani et al., 1987).

The consequences of programs not responding to individual client's choice on a first or subsequent contact is discussed in several studies in different parts of the world. Indirectly, the World Health Organization (WHO) free choice studies (WHO, 1980) indicated a fair amount of non-free choice (that is, all options were not indicated, and/or access was limited), considering that as many as 40 percent of women in different clinic sites would switch methods when they were provided with fuller information and more equal access. Clients otherwise committed to practicing contraception may be discouraged if they are not given usable information or the desired method is not easily available. For example, information from Niger (Maidouka, 1986) indicated that women who did not receive a method on the first visit did not return. A study of three clinics providing family planning services in Dakar, Senegal (Nichols et al., 1985) not only found a poor balance among the three methods provided but also found that nearly one-fifth of first-time visitors received no method at all. A conclusion of the study was: "It is evident that contraceptive dispensation at the three clinics is not tailored to the particular needs and reproductive intentions of the client populations, but rather to method availability and orientation of the respective clinic personnel" (1985: 274–275).

The effective denial of a chosen method can also result from "punitive quality" (discussed later), where unnecessarily high or irrelevant medical standards are set for the provision of methods. Bailey and Keller (1982), studying post-family-planning experience in St. Kitts, Nevis, and St. Vincent, found that 12 percent of women in their sample (who used methods other than the pill or the IUD) stopped using contraceptives because they preferred another method. This fact, combined with the low return rate to the clinic for scheduled appointments (85 percent of acceptors failed to keep all their scheduled appointments), makes clear the *importance of discussing the availability of a choice of methods on first contact*. Termination with a given method need not translate into "program termination" if clients are made aware at the outset of the range of options available and the readiness of the service to provide them.

Choice from the Client's Perspective

A number of analysts have creatively explored the factors influencing the individual's choice process. Bulatao (1985), for example, sees four dimensions to the individual's process: (1) balancing contraceptive goals with (2) their personal competence, (3) their evaluation of the contraceptive, and (4) contraceptive access (virtually solely the responsibility of the provider).

Hollerbach (1982) discusses the acceptability of the properties of methods (not programs). Users' assessments of contraceptives have many bases, the most important of which appear to be their effectiveness and their safety. Convenience and method of administration (that is, by injection, orally, and so on) are also important. The point here is that providers should understand the need for an intrinsic variety in the methods offered. For instance, a choice of three hormonal methods, although administered in different ways (for example, the pill, DMPA, and implants) can have similar side effects and therefore pose the same acceptability problems to users.

What is Informed Choice?

Finally, what comprises informed choice and how can it be measured? Do we need to develop culture-specific standards of "full and balanced information"? The information given to users must be practical and manageable. Thus, it is likely that trade-offs will occur between different elements of full and balanced information.[4]

Is it realistic to expect that clients want and require a full-scale lecture or will retain equally all information presented? Is it sufficient to go into detail with the method they select at the moment and emphasize the availability of other methods if their first choice becomes unacceptable after use? This is an important question for empirical investigation because many managers cite resource limits as a principal reason for neglecting superior information dissemination or counseling. Perhaps family planning programs should seek to impart to the client two central concepts—*choice and change,* with an emphasis on the following points:

- —There is a choice of methods, and all have distinctive risks and benefits.
- —Choices are provisional, and decisions are reversible (provided the method is); acceptance of a method is thus a trial.
- —Clients' needs and preferences often change over time.
- —Discontinuation is no failure on the part of the user or provider.
- —The present provider or others, upon referral, have the information and supplies to assist clients in maintaining their current choice or switching methods.

Perhaps these ideas, successfully delivered along with more in-depth information about the method selected, will sufficiently serve the client's interest in choice and support effective use.

Conclusion

In sum, choice is not only the first, but the fundamental element of providing quality in services. The evidence is overwhelming that a range of methods, competently provided, will attract more acceptors and provide for the switching among methods that is the foundation of satisfied and sustained use. The managerial task of providing choice is a complex one. Because "choice" of temporary methods is an ongoing affirmation and not the result of a one-time contact between client and a single provider, individual programs in the larger structure must carefully plan for expected fluctuations in individuals' needs. The ill-prepared introduction of a technology does not constitute the expansion of choice; choice implies the provision of methods up to some standard of technical and interpersonal care. Clients' own perception of whether they have received a choice is a subject for further study, but what is known of contraceptive use dynamics suggests that a long-term view is necessary and the provider's role should not be seen narrowly as the purveyor of technologies, but as a source of continuing support for individuals as their requirements change.

Information Given to Clients

Evolution in the Meaning of Information-Giving

The identification of the three aspects of information-giving (noted earlier) springs from a concept of technology that integrates the contraceptive device, procedure, or drug with the information given to the user about it.

The first aspect noted, the informational component of choice, insists that clients appreciate that a variety of methods are available, each with distinctive features. (This sharing of information is quite separate from promotion.)

The second aspect of giving information seeks to enable the user to employ the method effectively and to appreciate the method's potential to create physical changes, healthful or unhealthful feelings, and the impact of these experiences on daily activities and the most intimate aspects of partnerships. If clients do not retain usable and correct information, they cannot comply with the requirements of self-employed methods (condoms, spermicides, diaphragms, and oral contraceptives). If clinical methods, like IUDs and implants, are not explained sufficiently and their potential side effects appreciated, users are much more likely to discontinue use (Berelson, 1966). Unanticipated or unmanaged side effects lead to disappointed clients and result in discontinuation of contraceptive use, as Kreager (1977) persuasively documents.

This second aspect of giving information is closest to counseling in the sense that the provider and client seek a match from among the safe methods for a specific client. The provider should make clear that the use of a contraceptive technology has ramifications beyond simply regulating fertility. The individual is selecting a "therapy" that must mesh with his or her intimate sexual and social needs (see the more expanded discussion in Bruce, 1987). For example, many modern methods cause unpredictable bleeding. The impact of sporadic bleeding on religious custom, work habits, and sexual relations for many women is a vital consideration.

If this text had been written 15 or perhaps even 10 years ago, information-giving would have been called simply "screening." In the past, it was screening that received the most attention as a "quality" issue. In the late 1960s, the primary criteria of quality were the provider's professional standing and competence, as well as the care with which the client's health status and methods profile were matched. Questions were raised as to whether paramedical personnel would be as competent as medical doctors in identifying and preparing appropriate candidates for the use of modern methods, especially oral contraceptives (Rosenfield and Limcharoen, 1972). (It was found, and has been confirmed in diverse sites, that well-trained paramedical staff are equally able as, if not better than, physicians to communicate with clients about their health needs, take health histories, and identify clients with relative or absolute contraindications.)

In the 1980s and 1990s, the quality issues must go beyond concern about the ability of different levels of personnel to screen clients and move on to embrace a broader and possibly more difficult question: How far can screening go in ensuring informed choice and acceptability? Regarding informed choice, screening is an essential element insofar as it seeks to exclude from the pool of acceptors women or men who might experience dangerous health conditions as a result of specific contraceptive choices. For example, it is vital that women who are heavy smokers be advised against using oral contraceptives. As regards acceptability, however, and some adverse health effects, screening provides very little guidance. Paradoxically, the advances and the formulations of many modern methods that have rendered them clinically safer than they were originally have reduced the potential contribution that screening makes to satisfactory contraceptive use. Many modern method side effects that cause concern among users are often not medically dangerous, but rather are physical experiences that the user or the user's partner may not like. The present state of knowledge and practice, however, does not permit us to know with high levels of accuracy who will have breakthrough bleeding, headaches, or nausea with certain hormonal methods. Even where such events might be predicted, screening does not identify an individual's ability to tolerate them.

In sum, an individual's potential to experience and tolerate side effects is difficult to reliably anticipate and, thus, their occurrence is not measurably reduced through screening. The necessarily delayed knowledge on the part of the user, regarding problems she or he might have, underscores the importance of the third aspect of information giving: developing an appropriate expectation on the part of the client as to the service provider's forward role in giving advice, supplying methods, and referring other methods or service sites.

The clients' willingness to return to a service provider will relate in part to their comfort with the client/provider interchange, but recontact will also be promoted by specific content in the initial interview, such as the existence of a reappointment, the explicitness on the part of the information-giver that the client may have problems with the method selected, questions that need answering, or needs for reassurance. When delivering a method whose effectiveness is time-limited (such as medicated IUDs, implants, and injectable contraceptives) or that carries a risk of complications, the information that assures recontact is as essential to the client as is a description of the method and how to use it.

Clients' Information Levels and Program Performance

Little is known about the direct impact of information given to users on contraceptive prevalence. The effectiveness of mass media in altering contraceptive knowledge and behavior has been the subject of sometimes inconclusive research, much of which was conducted in the 1960s and 1970s. Recently, Lapham and Mauldin (1985) included extra-clinical information and education activities of an overall program as an indicator of program effort, but provided no assessments of the "strength" of the information given to clients one-to-one. In the 1990s mass media will likely be of growing importance, because the number of low-income families in Third World countries who have radio access has vastly increased since the first communication impact studies were conducted (Population Reports, 1986). There is great potential good to be yielded from broadcast information (as distinct from promotion) about contraception. Effective broadcasting could create an environment of accurate knowledge of a range of methods among potential family planning clients and encourage more effective self-care. However, regardless of its media environment, each program has to evaluate the adequacy of the information it directly imparts to clients. While no impact analyses are available of this dimension of service-provision, solid data exist supporting the contribution that sound and well-presented information makes to users' knowledge base and effective contraceptive behavior.

Evidence of the importance of providing written as well as oral information comes from small-scale studies, many of them conducted by the Program for Appropriate Technology in Health (PATH). These data (Haffey et al., 1984) indicate that most people remember messages better if the spoken word is reinforced by written or pictorial messages. Such visual materials support program staff in remembering and systematizing all they are to transmit, and they help the clients as well. For example, booklets for oral contraceptive users were introduced in a program in Bangladesh. One month after receiving this booklet, which described how to use oral contraceptives, 83 percent of the booklet recipients were still able to state when to start taking the pill, as opposed to only 16 percent of the control group, who received only verbal instructions. In Sierra Leone, PATH experimented with the value placed on written material. Seventy-eight percent of the women who received a booklet on the pill not only kept the booklet, but also used it to tell friends and relatives how and where to get more information.

The role of information in assuring clients and in contributing to contraceptive prevalence can be seen in a study by Keller (1973) of five Mexican family planning clinics. This study classified as "users" those patients who kept their last appointments within two months of their return date. "Deserters" were clients who were over two months late for their last appointment. This definition seems to be highly realistic, as it was found that 90 percent of women who did not return within two months also did not return within two years. The research demonstrated a strong relationship between the receipt of accurate information about methods, including anticipated side effects, and the propensity of clients to continue with methods and to resist negative, ill-founded rumors (Keller, 1973).

Another study, conducted in Bogotá (Measham, 1976), compared women who bought oral contraceptives from pharmacists or non-family planning outlets (called self-subscribers) with those who received pills from physicians (private or family planning units). Two points are interesting from the perspective of quality of information. Twice as many self-subscribers reported side effects than those obtaining orals from physicians. Lacking a reference point for medical review, almost two-thirds of the self-subscribers did not seek any help. This translated into slightly greater discontinuation rates among self-subscribers than among the users of traditional medical services. As the family planning program of India has increased the availability of spacing methods, the family planning association has intensified its concern with how to assure quality in the use of the IUD, a method with an uneven career in India. A recent study (Prabhavathi and Shenshadri, 1987) determined that incomplete information and poor follow-up led to measurably lower contraceptive continuation rates: ". . . Twelve-month life-table continuation rates are .6256 among those with incomplete information, compared to .7069 among those who were given more comprehensive information on side effects and other family planning methods prior to acceptance" (1987: 15).

Clients' and Providers' Misinformation

Since 1976 the number of self-subscribers of contraceptives has dramatically increased. Pharmacists worldwide play an expanded role in contraceptive distribution as women seek fertility regulation independent of the formal medical system and as the number of women who initially obtained contraceptives through clinical sources preferentially seek resupply from nonclinical outlets. A measure of this comes from Brazil, where the Brazil 1986 Demographic and Health Survey showed that about 93 percent of women there who use the pill got their supplies from pharmacists (IRD/Westinghouse, 1988). This and other surveys are confirming the increased access of women all over the world to commercially sold contraceptive supplies.

The public's expanded knowledge of contraceptives has not been paralleled by their knowledge of safe and effective use. Research from many countries has indicated extensive misunderstanding and misuse of methods with potentially serious consequences to clients and overall program effort. The task at hand is not simply to educate providers and potential clients better, but to cope with well-developed fears of specific contraceptives. Recent studies provide examples of how defective popular information about oral contraceptives is. In a study of eight developing countries, 50–70 percent of the women thought the pill posed considerable health risks (Grubb, 1987). Of special interest, and a measure of the consequence of misinformation, "26 to 60 percent of users (except in the Mexican sample) had stopped taking the pill because they worried about its safety and for each sample, a lower or similar percentage of never-users said they had not taken the pill for this reason" (Grubb, 1987: 318–319).

DeClerque et al. (1986) investigated rumor, misinformation, and oral contraceptive use in Egypt. They looked for, and found, a great range of concerns about the pill, including those linked to local cultural concepts. Their conclusion makes an important point regarding the reality of women's perceptions. High-dose pills (which continue to be distributed in parts of Egypt) and the poor health of women may indeed cause fatigue, which is verbalized as "weakness," among these women.

A study of family planning practice among nearly 1,800 women in a low-income area in Rio de Janeiro found that of the entire sample of family planning users, 34 percent were using pills; 23 percent of these were using pills incorrectly. Only 43 percent of the oral contraceptive users had received any medical orientation before purchasing the pills (Costa et al., 1987). The extent of self-prescription for this population resulted in serious misuse: 43 percent were smokers, the majority of whom smoked over ten cigarettes a day. Five percent of pill users were both heavy smokers and over 45 years of age.

A study conducted in Magdalena, Colombia, where most oral contraceptives are distributed by rural health promoters, provides evidence of a relationship between client's compliance and continuation with oral contraceptives and characteristics of the distribution system (Potter et al., 1987). Five hundred and seventy-two female users of oral contraceptives were interviewed three times. Twenty percent of them had already discontinued by the first or second interview (within two to six months after acceptance). Fifty-eight percent of the 340 current users used the oral contraceptives incorrectly within a two-week period. The promoters themselves were confused about key aspects of pill use, such as when to start the next pill packet. Only 54 percent knew the correct new time for a 21-day cycle and 44 percent for a 28-day cycle. Only 25 percent of the promoters had any information about how to treat nausea in the first three months.

Astonishingly poor provider information levels have also been documented in Guatemala (Townsend, 1987), Colombia (Townsend and Ojeda, 1985), and on baseline surveys conducted of pharmacists in different parts of Latin America (Rizo, 1979). Assuming providers' knowledge of methods can be improved—and experiments with community-based distributors (CBDs) and pharmacists have indicated that it can be—in what way does this increased knowledge translate into more contraceptive use? The limited data available provide no clear guidance. Research in Colombia (Townsend and Ojeda, 1985; Vernon and Ojeda, 1988) has not found a consistent relationship between better-informed providers and more sales of contraceptives. In these studies, however, though distributors' knowledge levels were increased, they were still very low, perhaps not reaching the threshold where effects can be seen. Further, the output measure that was selected—sales volume—can be misleading because some distributors sell wholesale while others sell only retail, and long-term distributors generally have a larger client load than do newer ones. These findings are not supplemented by information about clients' compliance with use regimes, clients' continuing use over a period of time, or client satisfaction.

Conclusion

These collective observations suggest that a revolution in information about contraception is needed. The pool of men and women who know the names of modern contraceptives and have used them appears to be ever-increasing. Yet, there persists in the general public and even among current clients poor knowledge of the proper use, risks, and benefits of contraceptives. Lack of information is a reason for discontinuing method use, and belief in rumors may be a deterrent to use altogether. Contact between client and provider after the first encounter is irregular. This is true because too little attention has been given to establishing continuity or follow-up mechanisms and because of clients' characteristics—their geographic mobility, the desire for privacy, and so forth—which may tend to make them move among supply points. Finally, despite some concerted efforts, gravely inadequate levels of information are found among primary providers in clinic, commercial, and community-centered systems alike.

Technical Competence

Technical competence is the element in the framework least easily judged by clients. Typically, clients evaluate providers more on the amount of time they spend with them and their caring attitude (Gay, 1980, 1988; Sung, 1977; Lynn et al., 1985) than their technical skills. Clients often do notice obviously dirty conditions, but they tend more to remember and report on discomfort and to differentiate between discomfort they did and did not expect. Even though lacking the ability to fully evaluate clinical competence, clients bear the consequences of poor technique in the form of unnecessary pain, infection, other serious side effects, and in some circumstances, death.

Clinical incompetence is rarely specifically reported but is often part of a wider pattern of poor program performance. Of all the literature reviewed for this paper, documented evidence of poor clinical procedure and its consequences was the most difficult to locate. (An exception to this is the detailed study of sterilization deaths in Bangladesh discussed below.) Assessments of unsanitary physical circumstances, poor observance of asepsis, gross errors in technique, or the application of inappropriate medical standards are made in writing in internal reports and other fugitive literature. However, citable material is rare. One reason for this is undoubtedly political; an evaluator who uncovers serious problems may not wish to publicize them because this may hamper collaboration with the provider in the urgent problem of improving care. It is also plausible, though, that the special status held by clinical practitioners, particularly M.D.s, may be another reason. As references in the rest of this article attest, candid evaluations can be found about the knowledge and abilities of CBDs, pharmacists, and even managers. Clinicians, however, seem to be largely protected from objective public reporting.

Technical Competence, Technology Transfer, and Program Performance

Despite the lack of documentation, strong indirect evidence of the impact of insufficiently trained providers can be detected in accounts of program or nationwide experience with specific contraceptive methods. Providers who are uncertain of their skills are sometimes reluctant to use them or, worse, apply them badly. Neither approach contributes to clients' health or increased contraceptive prevalence. Indeed, such providers' performance generates negative rumors about programs and methods. For example, the failure to successfully introduce the IUD in India was attributed to an insufficient program effort to train, field, and supervise staff:

> The IUD was an inexpensive, reversible, and effective method; it could be inserted by trained auxiliaries; it appeared to fit every requirement and was enthusiastically introduced. . . . But success and optimism were short-lived as inadequacies in pre-insertion checks, poor follow-up, medical complications, and grossly exaggerated rumors about complications led to high discontinuation rates and a seven-year slump in annual insertions [down from over 900,000 in 1966–67 to 370,000 in 1973–74] . . . The program had quite simply been rushed through without organizational preparation to cope with the known side effects, which turned out to be more widespread among the population of malnourished, anemic women who were not forewarned about what to expect (Soni, 1983: 41).

In Bangladesh, rumors about sterilization deaths led to an international effort to evaluate the sterilization program and document the death rate for tubectomies as well as vasectomies. The relatively high rates in 1979 (estimated at 19 per 100,000 tubectomies) of sterilization-related deaths were linked to inappropriate anesthetic practices and inadequate pre- and post-operative care. The evaluation resulted in major changes in program criteria as well as intensified criticism of incentive systems for both clients and referral agent. Subsequently, the death rate for tubectomy was halved, declining to 4.5 per 100,000 performed in 1983 (Cleland and Mauldin, 1987).

Less dramatic examples of the impact of provider competence on the differential acceptability and safety of contraceptive technologies are revealed during introduction studies. In evaluating new IUDs, it is necessary to distinguish the risks associated with the distinctive features of each new configuration, based on problems arising from the techniques of specific providers. When studies of the Levonorgestrel IUD (as yet unapproved by the FDA) began to reveal an unacceptably high perforation rate, investigation found that these rates were associated with specific centers where practice was of an insufficient standard, not traceable to some flaw in the device itself (Sivin, 1988). What have been generally rare in the literature are comparisons between classes of providers or morbidity and technical competence between program settings. Rather, comparison studies have largely been used to qualify new providers (such as nurse-midwives) to undertake procedures that had before been carried out exclusively by doctors. A strong case can be made, however, for more such studies of this kind. US-based studies of the pain and morbidity associated with IUD insertion found predictable differences (which were, nonetheless, important to verify) between the technical competence of inexperienced and experienced providers (Stumpf and Lenker, 1984).

A rare study, nearly ideal in its design, compares two broad areas in which DMPA was introduced in two distinct program settings. Phillips (1988) made clear the value of monitoring technical and managerial capacity of the delivery system when determining the potential reach of a new technology. The author concludes that DMPA's high discontinuation (in the extension areas) and consequent modest demographic impact in the extension areas of Bangladesh are traceable to "the absence of adequate mechanisms to ensure that the climate of care and service quality are generally sound" (Phillips, 1988: 22). In general, it appears that any method that demands a highly sophisticated technique is likely to be underutilized and/or misused in some settings.

Competency-Based Training

Training of providers is not synonymous with quality assurance. Problems of performance of nominally trained staff have led many family planning training agencies to adopt competency-based training where the standard for certification is achievement, whether measured through knowledge levels (of CBD workers or pharmacists, for example) or the mastery of clinical techniques under supervision (for example, IUD insertions, sterilization operations, and implant insertions and removals). Competency-based training requires the trainer to evaluate skill level, not time spent in a training program or numbers of procedures completed. If competency is to be continuously assured after the completion of the training sessions, the provider's knowledge and skill must be regularly used and periodically monitored.

The move to competency-based training is also favorable because it enables classes of providers without medical degrees to provide important services in the field. Midwives and other paramedical personnel can competently insert IUDs, give injections, perform menstrual regulation procedures, and in the future, will likely be able to insert and remove contraceptive implants. When it was first suggested that non-M.D. staff could insert IUDs, a number of case studies were done to compare their competence with that of M.D.s. In Iran, auxiliary midwives with one month's training in IUD insertion, including a minimum of 30 IUDs inserted under supervision, had similar rates of medical removal, expulsion without reinsertion, accidental pregnancy, and removal for personal reasons as did the doctors. The midwives had a slightly lower rate of "removal for personal reasons," which may indicate their superior communication skills (Zeighami et al., 1976).

Monitoring and Data Collection

A mix of monitoring techniques are needed to assess technical competence. A beginning may be to audit the state of clinic records for indications that screening was done, medical assessments made, whether complications were reported and how they were handled, and any other notable medical events (Donabedian, 1980). Another, more specialized form of self-reporting involves the production of case studies—detailed, systematic histories of a limited number of clients presenting a given complaint. Analysis of records can identify the client's background factors that led to the problem, the presenting symptoms, and the provider's initial and sequential responses. This system does not generate comparative data, but provides insight into problems for which remedies may be relatively easy. For example, an account of the case histories of ten pelvic inflammatory disease (PID) sufferers concluded that the ignorance among PID sufferers of the disease's origins, of its treatment, and of its likely path, was not remedied during client/provider interactions (Brown and Waddington, 1987).

These various methods of self-reporting and self-monitoring are valuable. However, assuring the observance of medical standards in most cases requires site visits and supervisory systems where field and clinic-based procedures are regularly observed. Sometimes providers have skills and knowledge but, for reasons not well understood, do not employ their skills or pass on their knowledge effectively. Trainees may know what aseptic technique is, but they may not give it enough importance, and/or are not in the circumstances to observe it. Sometimes providers go ahead with procedures they know to be potentially unsafe, even offensive, to clients. When workers' theoretical knowledge is sufficient for them to pass formal tests or interviews, insufficiencies can only be revealed through observation.

The ICDDR,B Extension Project employed observation as a means to pinpoint problems and improve performance. Government paramedics observed workers' rapport with clients, record-keeping, patient history-taking, and physical exams. Though these workers had received some 18 months of training, the observations revealed that none of the 19 workers observed took a history of the patient or her family, and only a minority washed their hands before physical examination (Nessa and Hurrell, 1985). The World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception published case studies of efforts by their affiliates in 15 developing countries to monitor the quality of care through units designed to operate within the specific management and cultural settings (WFHAAVSC, 1988). In addition to monitoring and observation, in some program settings—especially where contraceptive policies are being developed and reviewed and the introduction of additional methods is under consideration—it may be appropriate to collect reproductive health data on a subsample of clients. To date, very few such studies have been done. Studies of the health of a cross-section of program clients could provide valuable baseline information on women's health (the distribution of infection, sexually transmitted diseases, cervical erosion, menstrual disorders, and nonreproductive but relevant health indicators such as anemia). These data can be used to provide guidance on how and whether to provide specific methods. For example, the decision whether and how to offer the IUD could be positively influenced by the clinical knowledge of the incidence among prospective clients of reproductive tract infections (RTIs) and sexually transmitted diseases (STDs). Such studies could define the magnitude of morbidity resulting from inadequate services: incorrect prescription of contraceptives, improper aseptic procedures, infections, and insufficient follow-up. The results of these studies may also argue for an expanded array of diagnostic and treatment procedures in categorical family planning programs.

Wasserheit et al. (1989), in a study in Bangladesh, turned up 22 percent of almost 3,000 women reporting symptoms of RTIs. "Of the 472 symptomatic women, 68 percent had clinical or laboratory evidence of infection" (1989: 69). Important differences were noted in the reproductive health of users of certain contraceptives: IUD users and tubectomized women were four times as likely to report symptoms and seven times as likely to have examination-confirmed infections as nonusers. However, a number of these problem areas for women, of particular importance where other health services are so poor, might be addressed in revised and expanded family planning services.

Bang (1989), in a study of women in Gadchiroli, a district in the state of Maharashtra, India, examined 650 women (out of an eligible group of 1,102). Even taking into account the fact that "participants" in the study may have had features different from nonparticipants, she reported startling findings—a 92 percent prevalence of gynecological or sexual diseases. Extensive work must be done to confirm her results and to extend this type of baseline study to other areas in the subcontinent. A recent paper from Korea has also suggested very high potential levels of reproductive illness as perceived by women. About 58 percent of the respondents in a rural survey of women of reproductive age reported that they had significant and generally untreated gynecological problems, and 41 percent reported having had abortions (Women's Global Network on Reproductive Rights, 1987).

Punitive Quality

The inappropriate application of medical standards and the medicalization of some tasks, including insistence that they be performed only by specific and highly trained personnel, has led at times to a posture that might be termed *punitive quality*. We see numerous examples of women being denied control of their fertility because of overly restrictive criteria. For example, in one North African country, fully lactating women six weeks postpartum are denied immediate IUD insertion if they admit to having had sexual intercourse, on the grounds that they may be pregnant. In parts of West Africa, the oral contraceptive is only made available after a blood count is completed, and in some cases the client's request is reviewed by several physicians. In the "dubious practice" category, the bleeding patterns of hormonal contraceptive users are sometimes treated by giving estrogen or other drug regimes. In some parts of the world, women receiving sterilization are given a general anesthesia, when local anesthesia often is safer, provides adequate pain relief, and requires a shorter recovery period. Sometimes the barriers to service are justified by the phrase, "We want our women to have the very best care." Such claims should be examined when they effectively remove access to critical contraceptive care except for the most persistent or well-off.

Conclusion

The disparity between the articulated, often Western-based standards for technical competency and what is found in the field must be addressed through quality assessment. It is possible that the standards are not realistic or are inappropriately defined. For example, if one form of sterilizing procedure is not available, providers need to think about realistic alternatives. When a real risk exists that needles, trocars, and other clinical devices will be reused—and such reuse is dangerous—field staff must forthrightly deal with that risk by either rejecting altogether such behavior, or providing instructions to prevent it.

The technical competence required of many workers may be beyond their capacity. Perhaps a tiered system is in order, where staff are required to perform only up to a certain level, and then refer clients on to the next level, as needed. Interpersonal care and technical competence must come together, and providers must understand the importance of observing safe clinical standards. When only 9 of 19 workers wash their hands before inserting an IUD, it is reasonable to question whether their training included an appreciation of health consequences or the clients' needs.

Interpersonal Relations

The "interpersonal relations" element in the framework has been separated from the information given users because it is defined as the affective content of the client/provider transaction. It is this dimension, apart from the accuracy of the information given and the degree to which it is comprehended (important as it is), that may strongly influence clients' confidence in their own choices and ability, satisfaction with the services, and the probability of a return visit. What is desired is positive and productive exchange as perceived by the client. A recent review of counseling suggested that the desired attributes of the counselor were those of understanding, respect, and honesty (Population Reports, 1987). The client/provider contact should be characterized by two-way communication and question-asking, and flexible guidance (as opposed to authoritarianism) on the part of the provider. The desired outcome from this transaction, from the point of view of the provider, may be that the client reports a belief in the competence of the provider, trust of a personal nature, and a willingness to make contact again themselves, or even refer others.

Another affective dimension of the family planning worker's role is to *compensate for the technical limits of contraception* or logistical problems in accessing services. Empathetic information-giving may be as important as accuracy in allaying negative feelings about, for example, an implant insertion, the care with which diaphragms must be used, and so forth. In circumstances where women have to travel for special services about which they have some fear (like sterilization), a fieldworker accompanying the client compensates, in effect, for her discomfort with an unknown procedure. The workers' ability to discuss their own contraceptive experience or the ability to point out a healthy community member who is happy with a method responds to the client's reasonable worry: What will this method do to me and my health? The counselors provide, in effect, a guarantee of the technology by their presence and manner of communication (Simmons et al., 1988).

In many settings, the counselor cannot empower the client to make her own reproductive decisions unless she extends her intervention to the client's personal situation. For example, Simmons et al. (1988) document in Bangladesh the vital role of the family planning worker in helping women manage male authority in the family and in the community. The fieldworker's role is often one of ally and mediator, urging women to find their own voice and express themselves, and providing them with ideas they can use in arguing for their right to practice contraception. This task, for which workers are not formally prepared, is essential when women are in very inferior positions in the family and fear the consequences of unsanctioned contraception, which can include divorce or abandonment.

In assessing client/provider relations it is difficult, but essential, to separate the information-giving role (discussed above) from the counseling role. Reviewed below are scarce and generally small-scale qualitative studies of client/provider transactions, which unveil, analyze, and, in some cases, "grade" the emotional content of this interaction from the client's perspective.

Clients' Feelings

Mernissi (1975), in one of the early explorations of women's feelings about contraceptive services, described the indignities Moroccan women were asked to suffer, which included taking off their underpants and waiting in the hall for a pelvic examination. Scrimshaw (1976), in a series of studies of family planning services in Latin America, describes insults to women's modesty and sense of privacy resulting from having no separate interviewing rooms or curtains in examining rooms.

Other early literature that sought out factors that improved the workers' effectiveness and acceptability tested the hypothesis that clients were most comfortable with workers who resembled them in basic characteristics such as gender, marital status, and social class (the principle of homophily). Though this principle does not hold invariably, Repetto (1977) and many others have found positive support for it in a number of settings. Similarity between providers and clients may yield not only more contentment on the part of clients, but also different program outputs.

A recent review of worker performance in Bangladesh revealed different patterns of exchange between male and female workers and their clients. Female workers spent more time with clients and were more likely to recommend a range of methods and less likely to push women toward sterilization (Phillips et al., 1986). Research in Colombia indicated that nurses were more likely than physicians to change the methods of their patients. In addition, they were significantly more likely than physicians to keep their patients on conventional methods or even switch clients to "less effective" methods (Einhorn and Trias, 1978). It may have been that female nurses identified with their clients and trusted them to practice self-employed methods efficiently, and/or that they were at ease discussing the sexual dimensions of the use of barrier methods. The nurses' approach did not compromise use-effectiveness. In this particular study, the clients of physicians and nurses alike had high (85 percent and 84 percent, respectively) continuation rates at six months and only 3.2 percent of those in the physicians' group, compared with 2.7 percent of those in the nurses' group, became pregnant in that time.

Schuler et al. (1985) undertook a study in Nepal that evaluated the client/provider transaction, separating the accuracy and completeness of information given from the attitude and bias of the provider. In this study, "simulated" clients of different caste groups were asked to visit family planning providers. An unexpected result was the reluctance of the lower-class simulated clients to either make initial contact or return to services. They were fearful of the general service-providing system and vulnerable to the assaults on their status during their simulated interviews (in one case finding it difficult even to obtain the names of available contraceptive methods); members of this caste expected poor treatment and when they received it, were reluctant to criticize. Interviews were scored according to the degree of courtesy, consideration, attentiveness, and respect shown the client. Relevant behavior included greetings, whether the client was asked to sit down, the forms of speech with which he or she was addressed, and the ability to participate in a two-way dialogue, asking questions. The authors found a strong bias in the types of methods their "lower-class" clients were recommended; they were advised against using condoms and were directed to pills, IUDs, injectable contraceptives, and sterilization.

Among the dimensions of the client/provider relation in Latin America reviewed by Gay (1980) was the style (as opposed to the content) of information-giving. Rather than employing the time available for interpersonal exchange to reassure the client and make her more comfortable, the providers in effect undermined the client's confidence: "Clients are lectured on contraception with few opportunities for questions. The talk may consist of a morality lecture rather than a well-needed and valuable discussion of possible contraceptive side effects" (1980: 28). A study of family planning clinics in Honduras quoted a client who had been asked for her ideas about how to improve services. She said, "There should be more understanding for us humble people because we go there with great fear" (Mundigo, 1973: 14).

Management's Role in Promoting Better Interpersonal Relations

The examples given above, drawn from the far too limited research on client/provider transactions, affirm the importance to clients of privacy and observance of their modesty, bilateral interpersonal exchange without condescension, and some measure of identification between themselves and the provider. A caring attitude is important on the part of all personnel with whom clients deal. This caring attitude, or lack thereof, is not the product solely of the individual provider's personality. Rather, the ability of all classes of providers in the system to communicate well with clients is influenced by a whole stream of managerial decisions, beginning with the establishment of provider norms, training, job descriptions, structure of supervision, and rewards. Simmons et al. (1986) and Koblinsky et al. (1987), studying client/provider transactions in Asia, identify management and political factors that encourage or discourage effective interpersonal connections. In the two Matlab experiments mentioned earlier, contributing to the greater health and fertility impacts of the second experiment was an explicit change in program focus to what was defined as a *client orientation*. Workers were instructed to find solutions with individual women. This was accompanied by management decisions to increase the frequency of contact with clients, innovative record-keeping systems, and better supervision.

In contrast, workers' ability to respond sympathetically on an individual basis to clients can be undermined if they are working under the pressure of targets to attain demographic goals. The tasks workers are thus assigned often prove unreasonable. In early CBD projects, the worker acted as little more than a delivery service with a minimal communication role. The interpersonal content of this approach was probably best described in the case of an Egyptian CBD project, which boasted that each household contact required less than three minutes. Under target systems, the worker's service role can easily become secondary to meeting a numerical quota of specific method acceptors. An experiment undertaken in 1983–84 in the district of Rajastan State, India found that the target orientation was not conducive to systematic program operations. An innovative experiment was implemented in which workers analyzed client data and classified their clients into four groups, each requiring a distinctive approach. Though this approach did not directly correct the demographic ideology underlying the program, managers encouraged workers to understand more about clients' individual outlooks (Giridhar and Satia, 1986).

Similarly concerned over the impact of targeting systems and worker performance, some experiments were undertaken within the extension areas of Bangladesh to see if a new record-keeping system could improve the client orientation of workers. It was judged, however, that unless the target system was revised, the reorientation of staff could have only limited effects (Koblinsky, 1987).

Quantity and Quality of Care

The National Academy of Sciences' review of family planning effectiveness (Lapham and Simmons, 1987) identified the quantity of provider/client contact as another powerful determinant of the quality of care. The review concluded that in commercial, clinic-, and community-based systems alike a strong positive relationship exists between quantity and quality of contact. High levels of contact in commercial systems are welcome but largely unplanned. Over time, a relationship may spring up between druggists and their contraceptive customers that extends beyond supplying methods to providing broader health advice (Mitchell, 1984;

Assad and Katsha, 1981). The reverse is also true—because of druggists' and other personnel's role in giving informal health care, some seek them out when they first think about fertility control.

Community-based distribution systems have largely been devised to increase the accessibility of services. Depending on the worker/client caseload, the amount of time available for transactions may be very limited. For example, a study of work routines in Bangladesh found that even under the management's best projections, workers might have on the order of 11–14 minutes with each woman in the three-month period; the actual time proved to be closer to eight minutes because low worker densities meant that travel consumed a larger portion of the day, and many workers actually work fewer hours than scheduled (Koblinsky et al., 1987). (This and other analyses in Bangladesh were key in promoting the policy of doubling the number of female family planning workers so that they could provide more intensive service.) A review of programmatic and social determinants of client relations in South Asia (Simmons et al., 1986) concluded that the quantity of contact in the Bangladesh project under study (in the 1980s) was substantially higher than the India project study in the 1970s, with the result that higher worker-to-client ratios correlated with higher prevalence rates. Supervision, reward, and control systems all had a substantial bearing on client/provider transactions.

In the clinic setting, irrational or unorganized "patient flow"—that is, the efficiency with which patients are received, examined, and "flowed" through the system—can create or exacerbate poor interpersonal relations (Hudgins and Merino, 1988). This, in turn, may spring from poor scheduling of appointments, too few clinic hours, too few staff, and the misuse of some workers' time. Gay (1980) compiled alarming information on patient flow from multiple programs in Latin America. She observed, among other things, that in a Central American clinic average waiting time was of three hours and forty-five minutes (and up to six and a-half hours) for a first-time client, and one hour and fifteen minutes (and up to four hours) for a resupply client. On the other hand, the amount of time spent being served was astonishingly brief. Doctors typically saw women for a few minutes. One study in Tobago revealed women spent seconds rather than minutes with the doctor; 34 women received internal examinations in 25 minutes—including four IUD insertions and prescriptions for three cases of pelvic inflammatory disease (Cross and Arbor, 1977, as cited in Gay, 1980).

Sterilization camps in India and Nepal have also recorded astounding case loads per operating physician. Though the standard of care established suggests no more than 40 procedures per day, some physicians do up to 80 to 100 cases per day. Both provider competence and the quality of the provider/client transaction must be seriously compromised by such practice.

Conclusion

Despite all these negative accounts, many workers remain who are trusted by their clients even when they have irregular contraceptive supplies, too little time, and receive insufficient salaries. Yet, the service system has to develop understandable, observable, and affordable standards of interpersonal interaction, and alter program factors to favor it. The process for providers is perhaps two-tiered. In well-established programs, diagnostic work that begins with the client's perception of services is in order. Some of the techniques used to date include in-depth discussions with staff at all levels regarding their perception of the interpersonal process with clients, observation of client/provider transactions (Simmons et al., 1988), "simulated" clients (Schuler et al., 1985), patient flow studies (Hudgins and Merino, 1988), focus groups with clients (Folch-Lyon et al., 1981), and exit and post-service interviews. Much work needs to be done to devise appropriate questions that are specific enough and provide for scales of response (Huntington, 1988). Social marketing programs might explore the use of intercept studies (Green, 1988) in learning more about the client's experience of brief, but crucial, commercial transactions.

These sorts of studies will ultimately reveal a picture of what needs to be fixed from the client's perspective, although providers' knowledge of their own system and points of intervention will be vital to solving the problems presented. Among the likely interventions available are the revision of training approaches, the development of explicit criteria for interpersonal interaction, analysis of workers' case loads and distracting work pressures, increasing supervisory support for workers' interpersonal performance, and so forth. Progress in this area will rely upon program managers' willingness to orchestrate the interpersonal dimension of care as fervently as they do the technical dimension. For many clients, being treated badly is worse than receiving no care at all.

Continuity and Follow-up

In the early phases of family planning program development, most programs were clinic-based. Clients who did not reappear for their return visits were, in the best of these programs, recontacted by an outreach worker and encouraged to return. At the present time, though many women continue to be served by clinic-based systems, few of these programs conduct regular follow-up and perhaps more men and women in the world are served through commercial and CBD systems. Thus, the term "follow-up" has a somewhat dated and impractical ring to it for some, but the concept underlying it remains valuable.

Continuity of Use versus High Acceptance

Relevant to the operations of clinic-, commercial, and community-based systems is the broad objective of encouraging continuity of care to assure that after the first contact with a contraceptive provider, the trail does not end. More philosophically, a program's willingness to establish continuity or follow-up mechanisms is one measure of its longer-term commitment to individual welfare. The concluding discussion in the National Academy of Sciences report expresses it this way:

> Ultimately, we will propose that the test of quality care—the basis on which the client/provider transaction should be judged—lies not with its purely demographic consequences (e.g., measurable decline in fertility) or even in the maintenance of high levels of contraceptive use per se, but in the extent to which clients feel they have established a reliable relationship with a trusted provider and have achieved some substantial measure of safe, effective, and comfortable control over their reproductive capacity (Lapham and Simmons, 1987: 517).

The strongest practical argument for promoting continuity of use is the consequences to individual programs and national efforts of the failure to do so. Many family planning programs are designed with recruitment of clients more in mind than maintenance of use. Where demand for contraception is well mobilized, such an approach may not be fatal. But where modern contraceptive use is still an innovative behavior, the neglect of the pool of users has very serious consequences for overall program performance. Jain, in analyzing the interplay between acceptance and continuation rates, compares the consequences of high acceptance and low continuation with low but steady acceptance and high continuation. Using modeling to discern the relative impact of high acceptance versus high continuation, he finds that "programs can achieve better demographic results when they concentrate on a small number of annual acceptors and provide them with good care to enhance their satisfaction and thus to improve continuation rates, rather than trying to recruit a large number of acceptors at one time and not take care of them" (Jain, 1989: 6).

A handful of long-term follow-up studies have been conducted to give us a view of one-time clients' ongoing ability to control their fertility years after their first contact with formal delivery systems. Does discontinuity of program contact mean clients are no longer practicing contraception, are exposed to unwanted pregnancy, and/or have changed their fertility intentions? A classic follow-up study, conducted in Taiwan, charted the history of women who had originally had IUDs inserted in the late 1960s. Thirty months after insertion, only 28 percent still had the original device in place. Twenty-seven percent were not practicing contraception but had not become pregnant in that interval, and only 8 percent had become pregnant and carried to term. Former IUD clients had found other solutions in the form of other methods (though in limited supply at that time) and the use of abortion services, and, for a number of women, life circumstances had changed in the interim, leaving the client unexposed to pregnancy (Freedman and Takeshita, 1969: 347). The Philippines National Acceptance Survey (Laing and Alcantara, 1980) recorded all method continuation rates of 44 percent at 24 months and 21.3 percent at 60 months. Reviewing the reasons for such dramatic dynamics, the study found that 45 percent of discontinuation of the first method and 30 percent of discontinuation of the last method used was attributable to unmanaged side effects. Thirteen percent of those who discontinued use of first methods and 30 percent who discontinued use of the last method ended use when they became accidentally pregnant.

Role of Program in Short-Term Continuation

Shorter-term studies of "lapsed" users point to poor initial contact, ignorance of side effects and the possibility of switching methods, and inadequate follow-up as primary reasons for terminating the use of specific methods or contraception altogether. In general, these studies find very little discontinuation (within 12 months) traceable to changes in clients' intentions. Mundigo (1973) describes the follow-up of 158 women who had missed their return appointments by one to three months in clinics in Las Crucitas, Honduras. Twenty-six percent could not be recontacted because of sketchy information about their addresses. Only 85 women were found and, of these, 11 percent had become pregnant and 13 percent had been abandoned by their husbands in the intervening three months. Less than half of the 85 women contacted returned to the clinic, and only 30 percent of those who cited their concerns about side effects returned.

A post-family planning acceptance study in St. Vincent and St. Kitts-Nevis found that among women more than three months late for their last appointment, three-fourths in St. Kitts and 40 percent in St. Vincent were exposed to pregnancy. One-third of those who discontinued in St. Kitts, and one-fifth in St. Vincent, cited problems with their method. Another large proportion cited problems with clinic services and treatment by staff as deterring recontact (Bailey and Keller, 1982).

A recent study in Zambia (Whittaker and Coeytaux, 1987) indicated that a large proportion of the substantial number who discontinued (75 percent of users at the end of 12 months) could attribute their lapsed status to problems with the clinic, the availability of supplies, or the methods, all of which could have been improved through better management of resources.

Paralleling our poor knowledge of long-term contraceptive use dynamics is a general scarcity of information about the impacts of *specific* follow-up efforts on clients' behavior. A study in metro Manila of outreach versus non-outreach areas (both of which extended around clinic-based facilities where acceptors usually lived) recorded a higher contraceptive prevalence rate in the mid-60s compared to one in the mid-50s in the non-outreach areas (Zablan, 1985). The author also observed problems with the outreach system, including its inflexibility, which increased its cost in relation to its effectiveness. A family planning follow-up study conducted in Botswana in the late 1970s (Stephens, 1978), in response to a 65 percent discontinuation rate, found a positive correlation between active home visiting and compliance with follow-up health care.

An experimental program conducted in St. Vincent and The Grenadines (in response to the findings discussed above in Bailey and Keller, 1982) sought to reduce discontinuation by increasing clients' knowledge about contraceptives and their possible side effects, and by developing in clients and providers an awareness of alternative brands and method switching as preferable to abandoning contraceptive use altogether. The intervention designed gave additional training in side effect management counseling to community workers in two treatment areas. Whereas contraceptive prevalence at one year was not markedly different between control and treatment areas, clients' knowledge of contraceptives had notably increased, especially in the most intensive treatment area where more than 80 percent of the respondents knew about the pill, injection, IUD, female sterilization, and condoms. In the control area, a higher proportion of women (26 percent as opposed to 17 percent in the most intensive area) had experienced problems with their current method (Russell-Brown, 1985). A recently completed study in Mysore, India of 400 women who had IUDs inserted during the 1983–86 period found that women who discontinued IUD use within 12 months were significantly more likely to have received no follow-up than the average continuer (Prabhavathi and Shenshadri, 1987).

Improving Continuity of Use in Community-Based Programs

The studies discussed in the preceding section were conducted in program settings where clinic service is the focal point and field agents are employed as a supplementary service delivery approach. In programs where first contact and continuing service are to be provided through community-based links, the means available to encourage continuity of use are different. In these systems, neighborhoods rather than clinics are the service sites. In some systems the worker repeatedly contacts all women of reproductive age in a given area and in others the worker makes one pass at all the eligible households and recontacts only the acceptors for resupply purposes. This latter approach does less to generate a new base of users but may result when the density of workers to clients is so high that resupply of users is the minimum the worker can accomplish.

Community-based programs may have to approach the issue of continuity of care on two levels: that of the individual user's contraceptive practice and promoting a consistent and trusted relationship between fieldworkers and the community. The earliest community-based systems were designed neither to constantly support individual clients nor pick up clients on subsequent rounds. Continuous visiting to the same area, including to women who were not acceptors on earlier rounds, is not the same as follow-up, but a predictable worker visiting pattern is an excellent means to support ongoing clients and to pick up women whose need status has changed. In some parts of the world it is not unusual to find up to 30–50 percent of the women of reproductive age pregnant or lactating. High fertility rates, the instability of partnerships, and spousal separation owing to migration all contribute to sometimes rapid changes in clients' need status over the course of a year.

Successful field projects such as Concerned Women for Family Planning in Bangladesh rely upon frequent visits. An evaluation of this program cited factors responsible for its apparent success and included among them the numbers of methods available and the pattern of door-to-door service delivered on a regular basis (Pyle and Khair, 1982). An experimental CBD project in Morocco employed one to three visits to women who accepted contraceptives initially and those who did not in an area where contraceptive use was already relatively high. A significant number of women who did not accept on the first visit became acceptors on a second visit. The evaluation found that "revisitation is a very valuable procedure which added additional acceptors and likely contributed to the higher continuation rates than the single round survey" (Ministry of Public Health, Government of Morocco et al., 1981: iv). Through the observance of a predictable visiting schedule, the worker becomes a *reliable institutional factor* in women's lives and a source of information and help when they need it. (For elaboration of this concept, see Simmons et al., 1988.)

Making the Best Use of Existing Resources

Though clinic- and community-based programs may need additional resources to achieve the highest levels of continuation, more efficient use can be made of existing clinic and field-worker time. Patient flow studies often identify means both to increase the clinic volume and to decrease client waiting time (Hudgins and Merino, 1988). For example, clients seeking resupply or the answer to a quick question can be served separately from those having their initial intake. In field-oriented programs the density of workers and their distance from work sites and supervision are key determinants of the time spent in face-to-face contact with clients. Areal studies of contraceptive coverage underscore the strikingly low quantity of contact reported in areas where household visiting is meant to be a central program strategy. Misra et al. (1982) described a home visiting program in India that fell far short of its goals:

> Despite the existence of this program for a number of years, and the development of a work plan that should have permitted virtually every eligible couple to have been visited by at least one government worker on the question of family planning, fewer than 10 percent of the female respondents and less than 15 percent of the male respondents indicated that this had been the case (Misra et al., 1982: 386).

In the Philippines, a study of the effectiveness of outreach found that only 21 percent of the continuing users and 14 percent of the dropouts recalled a visit from an outreach worker (Laing and Alcantara, 1980). The shortfalls are attributed to travel time and substandard effort; many hours per week were unaccounted for by service effort. However, in the Philippines, as elsewhere, managers are also responsible for misusing workers' time by requiring them to fill out lengthy, redundant forms, largely unrelated to their care-giving role (Phillips et al., n.d.).

Clark et al. (1988), in an assessment of Bangladesh government health and family planning workers, studied not only rates of contact but the content of visits. In the study areas a great majority of women of reproductive age had had at least one visit and a substantial number had had more than two over one year. Between 44 and 84 percent of the visits by female workers and 15–90 percent of those of males involved some sort of substantive health discussion or transaction. However, only 8–12 percent of female welfare assistants' visits—those whose central concern was family planning service delivery—resulted in giving tangible service. An outstanding question worthy of further research is whether and how clients value these visits. Are the transaction opportunities with government workers valued by socially confined rural women?

The third major family planning system—commercial distribution—has made only limited attempts at follow-up, largely for research purposes. Some feedback loop has been established in some programs (notably Sri Lanka and Egypt) between the pharmacy and the clinic. In the case of Sri Lanka, at one time women who purchased oral contraceptives were given a list of physicians with whom they could check should they have difficulties. (Sri Lanka has a particularly low population–doctor ratio.) The social marketing program in Egypt allows women to buy IUDs, and they, too, are expected to make subsequent contact with a private physician or clinic. Intercept studies (interviewing users as they exit from purchasing contraceptives) have addressed themselves to brand loyalty and issues of cost, but have given less attention to the dynamics of continued use.

Conclusion

Over the last three decades, since the notion of follow-up was first formulated, the characteristics of programs and their clients have changed, in some cases dramatically. More and more women around the world are superficially knowledgable about contraceptives. More and more clients overall are self-referred and bypass formal medical advice altogether when initiating use. How can the media be used to inform the public, to support responsible self-care, and to direct widely dispersed clients to appropriate services? How can underfinanced programs use existing resources better to assist clients in managing their own fertility over time?

Supporting continuity of use among all clients may remain a desired goal, but priorities for specific follow-up must be set. Indiscriminate revisiting may waste time and undermine workers' morale. Distinctions should perhaps be made between the needs of a couple who state they want more children, a long-term established user of a provider-dependent method, and a young, new user of a self-employed method. The concept of *new* clients could be extended to include all those who are within their first year of use with a new method (not those who only made an initial visit). These individuals might benefit from orally and visually reinforced educational messages and receive specific follow-up methods early in the method-adoption process.

Where the health infrastructure is very weak, and services and workers scarce, follow-up visits for family planning might be integrated with those for other purposes. Stephens (1978) suggests the use of an integrated home-based record-keeping system wherein the health status of both adults and children is recorded. Such a procedure would reinforce the clients' rights to information about their own health and may be a practical solution. Stephens also reported that, in Botswana, 96 percent of the adults reliably retained their records and 99 percent retained those of household members under five years of age. Another means to serve women living in remote rural circumstances may be to network them, with their permission, in some way so that new users would be given the names of other women in their area using the same method. This could assist them in resupply and support.

Even without a heroic effort to win recontact, programs should focus on assisting clients in more effective self-care over the long term. Mass media—notably radio, displays at purchase points for contraceptives, package inserts, and so forth—could be employed to remind clients about the health dimensions of contraceptive use, such as having their IUDs or implants checked, discouraging pill use among heavy smokers, and the like. Effective follow-up and support of clients may demand some new resources, but they also require a stronger marketing sense and innovative thinking.

Appropriate Constellation of Services

Of all the elements in the framework discussed here, judgments about the adequacy of the "appropriate constellation of services" is least universal and most conditioned by context. Even within fairly limited geographic locations, contrasting configurations of services may be acceptable and even desirable. The possibilities are bounded only by clients' needs and managers' resources and imagination.

Given the possible variations, the evaluation of the appropriateness of the constellation of services is particularly value-laden. There are also several levels to this assessment. The most rudimentary level of judgment is whether the services are provided adequately within the articulated spectrum of the program. A second level of judgment is whether the service constellation is appropriate to the needs of the client population. If programs have determined to go beyond the conventional boundaries of family planning, to which of the many social forces and resources constraints have they responded? Experiments in expanding the constellation of services extend from the integration of conventional reproductive health services (MCH/FP) with less regularly offered, but vital, adjuncts—like the diagnosis and treatment of RTIs and STDs—to programs with an explicit social purpose. The latter category includes programs that use health services for women as their base but view the empowerment of women as an overall goal.

Simmons and Phillips (1987) analyzed the contrasting results of "vertical" (contraceptive and sterilization services only) and "integrated" programs—the latter combining family planning services with maternal and child health care services. They concluded: "Client populations have responded well to both integrated and vertical services. The lesson appears to be that people desire good services, irrespective of their specific combination" (1987: 204). While centering their evaluation on the impact of different combinations of services on family planning effectiveness, they call for a more detailed view of integration, focusing attention on the strength of the service-providing organization, however configured, and the impact of the constellation of services on worker performance as well as on client responses. Thus, a nominally "categorical" program (the Matlab Community Distribution Project or CDP) is faulted because of its limited quality and, therefore, limited acceptability, rather than for a basic flaw in the notion of vertical services. In contrast, the Family Planning Health Services Project (FPHSP) is not an unalloyed success because, the authors point out, it is selectively integrated, and some of the interventions perform badly, both in terms of negative effects on contraceptive prevalence and on organizational development.

The salient point of the Simmons and Phillips conclusions for the present discussion is that the appropriateness of the service constellation begins with an analysis of its competence. At the very least, any family planning or reproductive health service should include a sufficient standard such that immediately related health screening that bears on the prescription of contraceptives is available. Referring to the earlier discussion on technical competence, given the scientifically documented tendency of some contraceptives to either cause or exacerbate reproductive tract infections, including STDs, much greater attention should be paid to developing and deploying low-cost diagnosis and treatment of STDs within family planning service programs. If the broad credo of family planning services can be paralleled to that of medical doctors—"first do no harm"—family planning services should make every effort to be sure they are taking reasonable steps to improve the reproductive health of their clients.

Beyond assuring basic medical competence, programs should seek to learn how clients view their health and what they believe are the most pressing health needs directly related to their contraceptive use. Both practitioners' and researchers' experiences show that, in most settings, women see a close interrelation of all their reproductive functions; thus, it seems perfectly reasonable to combine prenatal advice, delivery, postpartum services, and diagnosis and treatment of gynecological infections. Mothers also view their children's health as an extension of their reproductive well-being (Better Health for Women and Children, 1987).

Germain (1987: 22) pulls these strands together in her definition of a reproductive health approach (as distinct from the approach underlying most FP and MCH programs) that would seek to enable Third World women to:

- regulate their own fertility safely and effectively by conceiving when desired, by terminating unwanted pregnancies, and by carrying wanted pregnancies to term;
- remain free of disease, disability, or death associated with reproduction or sexuality;
- bear and raise healthy children.

Though at this point in history few programs can perform all of these functions, such a concept provides a framework around which a broad service system could be organized.

Clients' views on the appropriate constellation of services can be gathered indirectly through analyzing textual accounts of their conversations with workers. Simmons et al. (1988) identified the scope of demands upon workers by recording conversations in the field. They found that service dialogues were sometimes thwarted because workers could not or would not respond to the client's salient crisis—the ill health of a child. Also, female clients asked for substantial assistance in overcoming male opposition to contraceptive use or fears of contraceptive technology. The responsive worker might devote considerable effort to convincing patriarchal authorities to permit contraceptive use, and traveling with a client for a distant sterilization or IUD insertion. The ICDDR,B program in the extension areas is using these conversations to discover clients' expectations of the workers' abilities. Where a discrepancy is detected between the workers' training, capacity, materials, and work incentives and clients' expectations, programs have an opportunity to improve the match.

If the first question to be asked in reviewing the service mix is, "Are we doing our job well?" and the second is, "Are we reasonably meeting our clients' expectations?", then the third question is an optimistic corollary of the second: "Is the program imparting to its clients a more conscious interest in their own health and other aspects of their well-being?" For example, a family planning program guided by and successfully transmitting the notion that women have the right to control their fertility is likely to bring to the surface women's interest in exercising power in other parts of their lives. Programs committed to responding to clients' perspectives, in this case women clients, may find a rationale for political involvement in women's rights issues (including the provision of safe abortion services), supplying clients with referrals for legal advice, economic services, or in some cases even developing economic adjuncts to their health service work.

Finally, a provider evaluating the overall service approach needs to be sensitive to another dimension: timing. The reproductive health approach articulated by Germain (1987) suggests a natural but intricate sequence of family planning, reproductive, and early childhood health services in a woman's lifetime. The basic document from the International Conference on Better Health for Women and Children through Family Planning puts it this way: "Human reproduction is a drama which begins with sexual intercourse, continues through pregnancy, reaches its climax in labor and delivery, and is only complete when the newborn baby has passed through the vulnerability of infancy and early childhood" (Better Health for Women and Children, 1987: 5–6).

In seeking to bring to life the meaning of "appropriate constellation of services" in this section some examples of soundly configured services are offered, and three natural linkages are highlighted: the linkage between contraceptive use and sexuality, between the mother's and child's needs in the immediate postpartum period, and between pregnancy termination and pregnancy prevention.

Sexuality and Contraceptive Use

A recent experiment to focus more attention on sexuality concerns in family planning programs was undertaken in a large public maternity hospital in Salvador Bahia, Brazil. The project offered all reversible contraceptive methods except the vaginal suppository, and referred clients for that method and for voluntary sterilization. It provided information and opportunities for clients to raise questions about human reproduction, contraceptive methods, and sexuality. Unusual emphasis was given to the counseling component. A service visit included four parts: individual pre-consultation with a nurse, group education discussion, medical exam and consultation, and post-consultation interview period. Though this comprehensive approach with extended education required new clients to arrive between 7:00 and 8:00 a.m. and remain for four to five hours, the service picked up tremendous demand based on word-of-mouth. Each day, 10–15 new family planning users were seen. The program ultimately was discontinued owing to political factors, but not before some evaluation had been done. Despite the length of time that clients had to spend at the hospital, they did not feel ill-served. On the contrary, clients highly valued the educational sessions, particularly the information on sexuality, as nearly half of them reported significant problems in their sexual lives. It was, in fact, the program's willingness to deal with this intimate concern that attracted them (Shepard, 1986).

A clinical research group in southern Brazil evolved a slightly different model when staff found that about 30 percent of the female family planning clients spontaneously mentioned sexuality concerns in their intake interviews. In a follow-up service experiment, 500 women were offered a series of four sessions of group sexuality counseling. Eighty-five percent responded favorably and attendance was very high. The 15 percent who did not choose to attend the sessions cited travel time, not the value of the program, as the reason (Goodson et al., 1988). With regard to contraceptive practice, 52 percent believed initially that their problems with sexuality were related to their method use. At the conclusion of the four-session program, only 12 percent saw such a relationship.

Sexuality concerns may be heightened in Brazil, but what is likely is that the increasing openness of the society, of social researchers, and of some providers is allowing concerns to surface that are characteristic of women all over the world. The paucity of information about Third World women's and men's sexuality concerns, and the unwillingness or inability of family planning services to deal with them, is often striking. Family power relations, sexuality, and contraceptive practice are intimately related; little information has been gathered from women and men in developing countries about their sexual feelings or practices. An indirect perspective on sexuality in developing countries was afforded through focus group sessions held in Mexico City in 1978, in which some women reported "a deep sense of depersonalization, humiliation, and physical dissatisfaction caused by their husbands' treatment during sexual relations" (Folch-Lyon et al., 1981). Other focus groups, conducted to learn more about natural family planning, have found that some women view the long periods of abstinence as "good," enjoying their removal from sexual availability (Jennings, 1988). For others, the required abstinence or change to noncoital sexual practice is a hardship that leads to abandonment of the method (Sharma and Sevick, 1988).

Other research, into clients' perspectives on the NORPLANT® implant system in Brazil, not only reported a high proportion of women experiencing menstrual irregularity, but further confirmed that most experiencing this bleeding (79 percent) indicated that bleeding discouraged sexual intercourse because of a fear of venereal disease, pain, infection, and a sense of modesty (Hardy, 1987). In the western countries, the role of sexual feelings has been increasingly acknowledged in contraceptive decision-making and use-effectiveness (Joffe, 1986; Spain, 1987). This acknowledgment has been translated into enhanced training for some family planning counselors. This approach can be fruitfully extended to Third World programs.

Postpartum Services

The definition of the appropriate services for mother and child in the immediate postpartum period has seemingly already been answered through the nominal integration of maternal and child health services and the International Postpartum Program (IPP) (1968 to 1970). Current postpartum programs rely upon the conventional wisdom of an earlier time, which accorded little importance to womens' views, the interaction between lactation and contraception, and the nature of the mother–child bond. The IPP posited that women exhausted from a recent delivery were ready to avoid a similar experience in the near future. The IPP itself found that women who had just delivered a baby might be interested to hear information about contraception, but that almost half of the contraceptive acceptors in the non-US sample took up contraception between the first and the twenty-fourth month postpartum, with a sharp peak at about six months (less than three months, 9 percent; four to twelve months, 49 percent; thirteen to thirty months, 27 percent; thirty months, 15 percent) (Zatuchni, 1970). A more recent exploration of adolescent postpartum clients found that their memory of the encounter with the family planning counselor was vague and in most cases nonexistent. Whereas many more low-income women are being attended during delivery, and many of these are delivering in hospitals, hospital stays are increasingly short (counted in hours) and the client is subject to numerous hospital protocols in a period when she may have a sort of amnesia (AMES, 1987).

Assuming women are ready at some point, but perhaps not immediately post-delivery, to receive information about contraceptives, the question then becomes how best to integrate maternal and child health services used by women. Six-week returns for mothers alone, for check-ups, often fall below the 50 percent level. This figure can be even worse for very young women whose contact with the service system is tenuous, or for high-parity mothers who feel they are too experienced or too pressed to seek official assistance. In general, women give priority to caring for their newborn rather than for themselves. However, a maternity hospital in Sfax, Tunisia, where a high proportion of the babies are delivered in that district (11,000 per year), has achieved a return rate of about 85 percent by combining the maternal postpartum visit, contraceptive care, and well-baby and immunization visits into one day. That day—the fortieth day after delivery (roughly six weeks)—also has significance within the Moslem culture (and others, as well), and is a follow-up appointment that women (and, increasingly, their husbands) are happy to keep (Coeytaux, 1989).

A further difficulty in most postpartum programs, even where contraception is offered in a manner sensitive to the timing and expectations of clients, is the medical policy content. Indeed, so absent was a concern with lactation and contraceptive interactions in much of the 1970s, that indiscriminate use of oral contraceptives in recently delivered women promoted by some contraceptive distribution programs may actually have increased the birth rate while inadvertently harming the health of infants. Winikoff et al. (1987), after conducting a review of common, and often misguided, postpartum contraceptive advice, developed a sourcebook for clinicians. After reviewing numerous studies of the fertility of lactating women, the authors concluded that, "While it is impossible to predict the exact week or month a breastfeeding woman ovulates, as long as she is fully breastfeeding and not menstruating, the chances of conceiving prior to three months postpartum is very slight" (1987: 12). The sourcebook provides specific protocols for the use of different contraceptives (and indicates the need for prohibiting use of some contraceptives during the lactation period), including the appropriate timing of their use.

Pregnancy Prevention and Pregnancy Termination

Putting aside political and ethical controversies, the service relationship between pregnancy prevention and pregnancy termination bears discussion. Many adolescents and numerous, but undocumented numbers of Third World women are motivated to make their first visit to a family planning clinic because of a fear about unwanted pregnancy or anxiety about their current pregnancy status. For example, when the New York State abortion law changed in the early 1970s, the caseload of Planned Parenthood of New York City doubled. However, pregnancy termination clients contributed only part of the increased caseload. Of 100 women coming to the clinic seeking pregnancy termination, as many as 40 percent were not pregnant and were able to be served with contraception. The pregnant 60 percent attained abortions and left with contraceptive methods. Even 17 years since that change in legal status, some 30 percent of the women who visit Planned Parenthood clinics believing they are pregnant discover they are not.[5] A service that cannot respond to a woman who is currently pregnant or believes she is pregnant neglects a troubled and very needy group of women and loses an important case-finding approach.

The Bangladesh Women's Health Coalition (BWHC) is representative of a very small group of comprehensive reproductive health services for women in Third World countries. In Bangladesh, it is estimated that 780,000 induced abortions are attempted every year by women desperate to prevent another birth. Perhaps 1 percent (7,800) may die from these unsafe, unsanitary procedures. This amounts to one-fourth to one-third of all women who die from pregnancy and childbirth in Bangladesh (Germain, 1988). In 1976, the government of Bangladesh began to endorse and directly provide "menstrual regulation" services through government health and family planning programs, as a means of ensuring that a woman at risk of pregnancy is not actually pregnant. Dixon-Mueller (1988) outlines three reasons rooted in women's health concepts that argue for the provision of such services. First, menstrual regulation is consistent with women's traditional beliefs and practices, including the use of herbal medicines for "bringing down the period" or washing out the uterus. These are viewed as necessary to maintain good reproductive health. Second, consonant with the first, this method of fertility control is more natural and easily understood than modern mechanisms such as the intrauterine device, oral contraceptives, injections, and sterilization. Third, menstrual regulation is a back-up to contraceptive failure that can result from misinformation about other methods and inexperience in their use. We might add a fourth: Menstrual regulation and other forms of early abortion are very safe and, in some circumstances, for some women, pregnancy termination following contraceptive failure is safer than using oral contraceptives or intrauterine devices.

The Bangladesh Women's Health Coalition is the only nongovernmental organization in Bangladesh currently providing these services. BWHC offers a range of contraceptive services, menstrual regulation, referral for sterilization, and, in addition, treatment of women and children for primary illnesses like dysentery, scabies, upper respiratory tract infections, eye infections, and anemia. Immunizations against childhood diseases are also provided.

The services of the six BWHC clinics are of uncommonly high quality, are reasonably priced for their clients, and, even taking into consideration the subsidy provided, are less costly per unit of fertility control rendered than the government program (Kay, 1988). Though menstrual regulation is a vital part of the BWHC's services and the initial one offered in some of its six clinics, it is not the one in most demand. Menstrual regulation comprises not more than 10 percent of services in any location. In addition, the balance of maternal–child health, contraceptive menstrual regulation, and other services offered by each clinic is highly varied and responds to client demand. The urban centers tend to provide more specialized reproductive health care and less child care, and the rural clinics tend to offer more child care. Yet, in a month each center provides between 80 and 100 menstrual regulation procedures. A very high proportion of these clients (90 percent) leave with a contraceptive method. (This is consistent with findings from other Third World clinics that incorporate menstrual regulation, where 75 percent or more of clients accept a method post-procedure; see Germain, 1988). Because the criteria for menstrual regulation are restrictive (less than 10 weeks must have passed since the woman's last menstrual period), a woman who does not qualify is offered prenatal care. Following delivery, she is eligible for contraceptive and child health services.

This summary of the Coalition's comprehensive approach does not do justice to the richness of the program. However, it is an example of the naturalness with which pregnancy termination—or "assurance of non-pregnancy," as it is called—can be integrated with contraceptive care as well as other reproductive and child health care services.

Conclusion

Though a woman's needs over the course of her lifetime are biologically as well as psychologically integrated, for the most part, services segment these needs, sometimes in an extreme and detrimental way. A pregnant woman may not receive information about contraception or pregnancy termination. A recently delivered mother is urged to accept contraception when she is psychologically focused on the health of the infant, physically exhausted from delivery, anovulatory, and not likely to be sexually active for six weeks postpartum. A fully lactating woman seeking contraception several months postpartum is denied the service because it is believed she might have been exposed to pregnancy and her menses have not resumed. A sexually active adolescent is denied contraceptive information because she is a minor and only becomes a social senior by experiencing pregnancy and/or marriage, forced or not. Contradictions abound in our programming approach. The appropriate constellation of services is one that responds to clients' rhythms and health concepts, rather than inflexible medical demarcations of where a "need" begins and where it ends.

Practical Applications of the Framework

The framework discussed in this paper is a starting point, meant to provoke questions. This section proposes ways in which the framework might be used as a practical and analytic tool.

On no account should the framework be used in any rigid manner, and, accordingly, little attempt has been made to establish a balance between the six interconnected elements. "Choice" is the first element listed because it is so fundamental; a choice of methods is a virtual precondition for achieving quality of care. Beyond this, however, each program may choose to give different emphases to other elements depending upon the maturity of the program, its political history, and so forth. In a recent exercise with trainees of a Johns Hopkins University short-term training program for family planning program managers, participants were asked which of the six elements they felt needed attention in their settings. The majority felt that "information given to users" and "follow-up and continuity mechanisms" were the most neglected areas. This group was drawn predominantly from Africa. Another group, or those representing other regions, might have other priorities.

Though the framework seeks to cover most aspects of care, it still may not be comprehensive enough for all purposes. For example, the International Planned Parenthood Federation/Western Hemisphere Region, Inc. has created its own framework drawing on these six elements, but supplementing them with points vital to its own specific operations. One of the most obvious limitations of the model presented here is that it does not directly deal with issues of access except insofar as choice assumes access (a point discussed in the introduction).

In discussions with managers to date, it has been necessary to "locate" observations regarding the ways in which care can be: (1) described, and/or (2) improved. Issues easily overlap in discussion. Therefore, four major questions for service providers that need to be answered are now laid out:

—What is the standard of care you wish to offer?
—Have you prepared adequately to offer a (given) standard?
—Are clients receiving the quality of care intended?
—What is the impact of the care given?

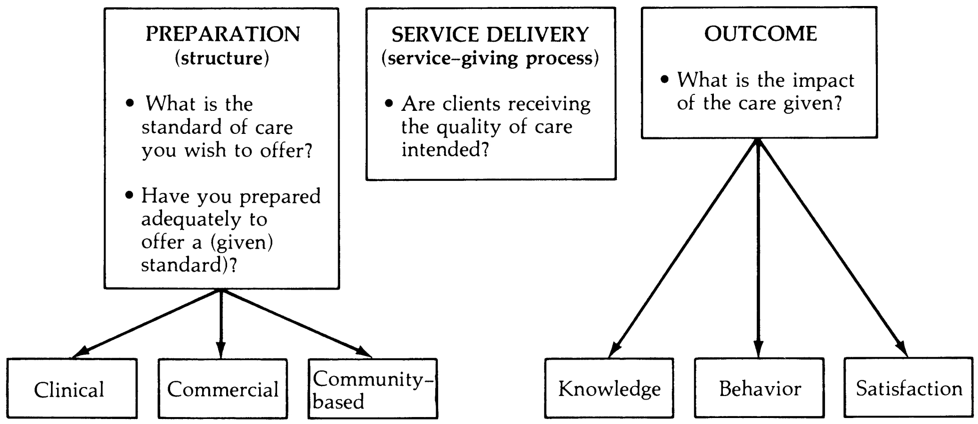
Donabedian (1988) again provides some guidance for mapping these concerns. Though his nomenclature is somewhat different from my own preferred nomenclature, he locates quality issues in structure, process, or outcome. In Figure 2, the six elements discussed in the present framework are listed in the note, and across the top are three different observation points.

Preparation

In the "Preparation" column, which Donabedian might call "structure," the first two questions (listed above) are addressed. These questions should be answered from the perspective of the six elements. Without detailing the steps necessary, the process might include a review of whether, for example, the facility or program is well equipped, whether the staff have been trained in both technical and interpersonal dimensions of care, whether the information used by the program in setting norms is accurate and appropriate, whether supplies and other aspects of logistics are well prepared, and so on. Some frequently overlooked questions that could be asked in this inventory are whether the information imparted in training has been absorbed by workers (Foreit and Leon, forthcoming) and whether they have achieved some level of competence. Assessments to be conducted by management (or outsiders, donors, and others), which look at program effort, would be located at this first "preparation" point.

The preparation required to offer clinical, commercial, or community-based services will differ, and so these three subcategories are illustrated in the first column, too. Background policy factors such as the stated rationale for making family planning services legal and available, overall resource allocations to the public sector, and support for choice of methods through import and pricing mechanisms could also be included here as defining to some extent the implicit standards of care and the quality of the care delivered.

Figure 2 Quality issues to be addressed in family planning programs at the points of preparation, service delivery, and outcome



Note: The "preparation" and "service delivery" questions should be asked with reference to the six elements: choice, information to users, technical competence, interpersonal relations, follow-up mechanisms, and constellation of services.

Service Delivery

The second column, "service delivery," is the logical next step after "preparation" (called "process" by Donabedian). Relatively few studies of family planning care look at the *process* of service-giving. Having prepared the program structure to provide care of a specified quality, what actually happens? Viewing service-giving is difficult because it encompasses so much; establishing a neutral point of observation is almost impossible, and some considerable thought needs to be given to the ends achieved by invading the care-giving process for monitoring or research purposes. Yet, viewing the client/provider transaction is essential. Indirect observation can be made by interviewing both providers and clients, after services have been provided, as to their memory of their interaction. More direct techniques include tape recording, videotaping, and observation by monitors. This sort of research can be used to determine whether all the preparation to provide choice, present accurate information, competently observe technical protocols, relate sympathetically to clients, give follow-up messages, and so forth are handled according to program norms. (See Nessa and Hurell, 1985, for example.) The service transaction reveals in condensed form the immediate outcome of all the preparation. Simmons and others view the client/provider transaction as the appropriate end-point of family planning program management. Indicators of the adequacy of the transactions will be considerably more difficult to derive than those at the programmatic or structural level. Indicators of the adequacy of preparation can flow from policy and centralized norms. However, judgments about the adequacy of service-giving, especially its interpersonal dimensions, are more qualitative. A range of client transactions will have to be observed, as different clients have different needs. For example, whereas denial of a person's choice may be observed in a single encounter, numerous observations will be necessary to see a pattern of limiting choice.

These observations of care-giving are also vital to learn what is actually demanded of workers in the service process. Very often, workers make heroic efforts to meet clients' needs, but these are activities for which they are neither trained nor rewarded. The reverse can also be true—workers are prepared and fielded with a norm in mind, which they apparently willfully ignore. The mission of observation is not punitive, it is practical. Viewing the service-giving process can help managers know whether the tasks established for their workers are achievable and match the demands made upon them by clients.

Outcomes

Finally, the third column in Figure 2 represents outcomes. Within this vertical dimension, three encompassing subjects—clients' knowledge, behavior, and satisfaction—could possibly be viewed along a timeline. Nearer-term outcomes could include clients' knowledgable use of their method, knowledge of alternatives (including sources), and clients' willingness to return to the provider or to refer others. Longer-term client-based indicators of the quality of care delivered could include clients' use-effectiveness (at 12 months) with self-employed methods, or clients' ability over time (for example, 24 months) to manage their own fertility through continuous use of one method or through switching. Ultimately, the longest-term objective would be clients' ability to attain their own stated wishes regarding regulation of their fertility—the wanted or unwanted status of pregnancies in the period after first service contact.

Program managers' interest in outcomes may go beyond these outcome indicators. To date, probing large-scale research on client outcomes has not been undertaken. Some questions have been asked in the World Fertility Survey and in the Demographic and Health Surveys. These have tended to look for broad indications of both access and satisfaction with services. Often, the questions posed are at a general level and elicit courtesy responses. Both these factors may result in generally positive, but not necessarily meaningful, results. When the questions are pared down into more specific areas (which can be organized by the elements)—for example, "Apart from the method you selected, were you given information on other methods? If yes, which ones?"—more realistic answers may be given. At issue here is how soon after the service experience the question is asked, whether questions are refined enough to elicit realistic and meaningful answers, and finally, whether scales are provided so that users' answers reflect an accurate view of their feelings. For example, Huntington (1988) is searching for ways to go beyond the discriminatory power of scales, using verbal cues such as exclamations, and some nonverbal ones such as gestures, as well.

Evaluating the Elements

Though the bias of some analysts may be to separate out observation of the six elements across the continuum presented in Figure 2 (for example, studying choice at the level of preparation, and interpersonal relations at the level of service delivery), my own bias would be to consider each of the six elements as observable (with different indicators) at each of these three points. With regard to choice, for example, an indicator under "preparation" would be the existence of provider norms, availability of supplies, and training staff to offer a balanced choice. At the "service delivery" stage, direct reports or observations of transactions could reveal whether people were being given sufficient information to make voluntary and informed decisions and whether they had access to the necessary supplies at affordable cost. Under "outcome," a mixture of information derived from questions to individual clients (for example, "Were you offered a choice of methods?" or "Were you offered information on a variety of methods?") and program-level indicators (for example, the distribution of method choice by clients' age, parity, and reproductive intention) could be used.

This framework may be used by those who are beginning to design their service system and develop their program norms. For example, at the Planned Parenthood Association of Zambia's family planning center, the staff determined their service-giving goals using the six elements. They separated outcomes desired for clients from those they wished for the program. "Client-oriented key results" included:

- —Clients receive information, education, communication, and counseling services that help them to plan their families and reproductive lives, identify and manage side effects, and know what services the clinic can provide.
- —Clients receive competent care. They don't become pregnant accidentally and don't get sick. They receive consistent, supportive, appropriate management of side effects and complications.
- —Clients receive care, at a visit and over the course of a year, with an appropriate and a minimal expenditure of their time.
- —Clients receive prompt and appropriate care from external agencies.

This example demonstrates that *programs can and should be explicit about their quality goals.* As no one standard of desired quality exists, a given program in the pursuit of "acceptable" quality in their context may decide to take a shortcut with one dimension or another. Resource limits may dictate choices. Managers need to be explicit about what decisions have been made, and why.

A well-established program could presumably use the six elements in this framework to begin the process of engaging staff in discussing the current level of care. In such an exercise, each of the six elements could be used as a discussion topic with managers and direct service-giving staff, using these providers' views initially to pinpoint difficulties. In all cases, however, this information is necessarily supplemented by feedback from clients.

Finally, the framework may have research purposes. As acknowledged earlier, it is unlikely that quality of care will receive all the attention it deserves based simply on principles of human rights and welfare. A large number of donors and others in the field continue to desire information about the level of care that correlates with specific types of performance and they may, in the future, seek to know whether improvements in quality of care will translate into an aggregate benefit beyond individuals' satisfaction with services. The desired aggregate will be, for some, higher levels of acceptance and more sustained contraceptive use.

The national director of family planning may wish to understand the role of differences in the quality of services provided as a determinant of performance at the district or program level. This may include a better understanding of the role of differences in quality of services provided (a research project in India under the direction of Visaria and Jain is exploring this issue). Thus, the "outcome" measures of interest in this type of analysis could include both aggregate-level indexes of contraceptive behavior and clients' qualitative assessments of services received.

In general, for quality of care to be a useful research topic, concepts of program effort would need to be expanded to encompass more technical interpersonal elements of care. Kumar et al. (1989) have developed an assessment approach for clinic-centered programs. Using the framework, within each type of program (clinic-based, field-based, community-based, commercially based), slightly different indicators might be developed, at least in column one (preparation), where the service-giving setting is diverse. There may also be some diversity at the level of service delivery. For example, client/provider exchanges are expected to contrast among those in a clinic, between field-worker and client in the community, and between purchasers of contraceptives and commercial distributors. However, in the third column of Figure 2 (outcomes) a convergence of indicators is expected, insofar as the goal of all programs should be fairly similar—that is, providing people with enough information and supplies to manage their fertility with relative safety, effectiveness, and satisfaction.

Acknowledgments

The author would like to express appreciation to the Quality of Care Advisory Committee and especially Ruth Simmons, Deborah Rogow, Ruth Dixon-Mueller, Adrienne Germain, and her colleagues Anrudh Jain, George Brown, and Beverly Winikoff for their comments on an earlier draft. Special gratitude to Mary Ann Castle for her resourceful research assistance, to Alice Tufel Lesser for her editing assistance, and to Virginia Kallianes for her skill in typing and assembling this and earlier drafts.

Notes

A slightly expanded version of this paper was published originally as a Population Council Programs Division Working Paper, No. 1 (May 1989).

1 Ruth Simmons employed Donabedian's approach to quality of care in prefacing a discussion of her work at the second meeting of the Quality of Care Advisory Committee, April 1987.

2 Jim Foreit relayed this report from work he had undertaken in Lima, Peru in 1988.

3 NORPLANT® is the registered trademark of the Population Council for subdermal contraceptive implants.

4 This discussion is drawn from an earlier paper by Bruce (1986).

5 These data are from personal knowledge. I served as Director of Community Studies and Evaluation for Planned Parenthood of New York City in the first two years after the change in the New York State abortion law (1971–73). We regularly calculated the proportion of women seeking abortion services who were not found to be pregnant. According to Alfred Moran, Executive Director of Planned Parenthood of New York City (1966–89), in recent times the proportion of women who seek abortion services but are found not to be pregnant, is 30 percent.

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Exploratory interview topic guide

Dialysis Centre personnel

- Profile of patients attending the centre (Probe: age group, gender, socio economic background including education and employment, illness duration)
- What kind of services are offered at the centre?
  Probe: Dialysis, patient counselling, meeting and psycho education for family members, group therapy or peer education for patients/ family members, Other services such as lab, pharmacy, etc.
- What type of dialysis are conducted? (If more than one, what are the criteria to choose one method to other?)
- How about patient adherence? (regularity with doctor's appointment, dialysis session, other therapy sessions) In people are not adherent, what are the reasons cited by them to miss a session?
- What is the procedure for admission? (referral from other centres, patient walk in, inclusion exclusion criteria)
- What are the major issues discussed by patients here?
- If a patient expresses his inability to pay for dialysis, are there any mechanisms to assist him? (probe: reduction in fees, referral other centres offering free services, exploring other options for subsidies etc?
- What are the major trends with CKD that you have observed over time? (example, increase or decrease in number patients, any patterns with regards to socio economic status, or risk factors)
- What are your views on the services offered here, and in other centres ? What are the key issues you have noticed? (in terms of HR, quality of services offered, fee for services etc)

Interview topic guide – patients

- Illness details- how did CKD get detected? Duration of illness
- Care seeking trajectory- from the detection of CKD till now
- Economic aspects- treatment cost, additional expenses- how treatment costs are managed
- Views on the services offered at different centres- staff attitude and communication, information given by the staff, views on support services etc
- Family/social support available
- Suggestions to improve the services for CKD patients

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

Title and abstract

	Page/line no(s).
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	1

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	1-2
Purpose or research question - Purpose of the study and specific objectives or questions	3

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	3
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	-
Context - Setting/site and salient contextual factors; rationale**	3
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	3
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	4
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	3-4

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	3-4
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	3-4
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	3-4
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	3-4
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	3-4

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	4-10
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	4-10

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	10-11
Limitations - Trustworthiness and limitations of findings	11

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	NA
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	NA

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014 DOI: 10.1097/ACM.0000000000000388