

A PARITY DEPENDENT MODEL FOR NUMBER OF BIRTHS

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ABSTRACT

A model have been derived in this paper for number of births to a female during a time interval $(0, T)$ of length T since marriage assuming the conception rate, incidence of foetal wastages and chances of onset of sterility following a child birth to be parity dependent and shown its application to evaluate a family planning programme in the terms of changes in the child bearing pattern. The use of the model is also illustrated through examples.

The models for describing the number of conceptions or children born to a female during a given period have received considerable attention during the last three decades. A critical review of such models and their applications are given in Sheps and Menken, Mode and Singh. Renewal theory is frequently used in constructing these models because of underlying simplicity in mathematical analysis. The models developed by Henry, Dandekar, Brass, Singh, Perrin and Sheps, Sheps and Perrin and others are examples which are derived under the assumptions of a renewal process. These models have been used to evaluate the impact of family planning programmes. However, the applications of these models are limited because of the restrictive assumptions that the parameters are homogeneous in time i.e., independent of factors such as age, parity, marital duration etc. Empirical researches suggest that at least some of the parameters of reproduction could be a function of these factors. In order to apply the models to data for longer durations the variation in the parameters with respect to one or more of such factors should be taken into account. Family planning methods further, intervene the natural reproduction process bring

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change in child bearing pattern either by altering the fecundability through contraceptive practice or by changing the probability of a conception ending in a live birth through changing the abortion rate, or by shortening the reproductive span through sterilisation. Adoption of a method for spacing or limitation of family depends, among other things, on the demographic characteristics of a couple. Therefore, in order to describe observed distribution of births when observational period is large or to study the change in fertility due to family planning programme, it is necessary to develop suitable models taking into account the variation in the parameters with age, parity, etc. Singh attempted this problem by assuming conception rate to depend on time. Considering human reproduction as a non-homogeneous process, wherein the transition from fecundable to non-susceptible state and vice-versa both depending on female's age and also the latter on duration of pregnancy, Chiang derived a general formula for the number of pregnancies to a female during a given period. However, the densities for the time dependent models are very much involved and it is difficult to give suitable procedures for estimation. Alternatively, Singh et al. attempted this problem by assuming the conception rate to be a function of parity. This model assumes one to one correspondence between a conception and a live birth. Model extended the model proposed by Perrin and Sheps by considering the parameters both age and parity dependent. He gave only general expressions.

A model have been derived in this paper for number of births to a female during a time interval $(0, T)$ of length T since marriage assuming the conception rate, incidence of foetal losses and chance of onset of sterility following a child birth to be parity dependent (Section 2) and shown its application to evaluate a family planning programme in terms of changes in child bearing pattern (Section 3).

The Model

Let $X(t)$, $0 \leq t \leq T$, denote the number of live births to a female during period $(0, t)$ of length t since marriage. In this section the distribution of $X(T)$ is derived under the following assumptions:

- i. $X(0) = 0$, the female is susceptible to conception at the beginning of the observational period and has led a married life throughout the period of observation.

- ii. Given $X(t) = i$ and that she is susceptible to conception at time t , the probability of a conception during the time interval $(t, t + \Delta t)$ is $m_i \Delta t + O(\Delta t)$; $m_i > 0$ ($i = 0, 1, 2, \dots$).
- iii. A conception ends in either a live birth or a foetal loss. Let $(1 - \theta_i)$ be the probability that a conception to a woman of parity i will end in a foetal loss, $0 < \theta_i \leq 1$, ($i = 0, 1, 2, \dots$).
- iv. Let h_i and h_i' be the lengths of non-susceptible periods associated with a conception leading to the i th live birth and each of the foetal losses occurring between i th and $(i + 1)$ th parity, where h_j is constant and h_i is a random variable which follows an exponential distribution with mean $1/c_i$ ($c_i > 0$). All h 's are assumed to be same and equal to h (say).
- v. Let $(1 - a_0)$ be the probability that the female is primarily sterile or chooses to be so during $(0, T)$ and a_0 is the probability that she is fecund at marriage. Again let $(1 - a_i)$ be the probability that she becomes sterile or chooses to be so till the end of the observational period following the termination of the i th live birth. This may be either due to secondary sterility or due to the adoption of one of the family planning methods of 100 per cent effectiveness.

Let the conceptions resulting in successive live births occur at times Z_r , $r = 1, 2, \dots$ ($Z_0 = 0$) and let $T_r = Z_{r+1} - Z_r$ ($r \geq 0$) denotes the time between the r th (marriage when $r = 0$) and $(r+1)$ th live birth conception. From the assumptions of the model it can be seen that the $T_0, T_1, T_2, \dots$ etc. are mutually independent.

If a woman had n foetal losses between r th and $(r + 1)$ th parity, T_r ($r > 0$) can be written as the sum of $(2n + 2)$ independent random variables as follows:

$$T_{r/n} = \sum_{j=1}^{n+1} X_{rj} + \sum_{j=1}^n Y_{rj} + h; \quad r > 0$$

and T_0 can be written as the sum of $(2n+1)$ independent random variables

$$T_0/n = \sum_{j=1}^{n+1} X_{0j} + \sum_{j=1}^n Y_{0j} , \quad (2)$$

since the starting point of T_0 is not a rest period as in the case of other T_r s.

X_{01} is the time of first conception and X_{rj} ($j = 1, 2, \dots$; $r = 0, 1, 2, \dots$; except $r = 0$ and $j = 1$) is the time between j th conception following r th live birth conception (marriage when $r = 0$) and the resumption of menstruation following the previous pregnancy and Y_{rj} is the duration of non-susceptible period associated with the j th foetal loss following r th live birth.

Under the assumptions of the model, it is evident that, for each r , $\{X_{rj}; j = 1, 2, \dots\}$ is a sequence of independent and identically distributed random variables with the distribution function

$$F_r(t) = 1 - e^{-m_r t} , \quad t > 0, r = 1, 2, \dots \quad (3)$$

and $\{Y_{rj}; j = 1, 2, \dots\}$ is a sequence of independent and identically distributed random variables with the distribution function

$$K_r(t) = 1 - e^{-c_r t} , \quad t > 0, r = 1, 2, \dots \quad (4)$$

and the sequences $\{X_{rj}; j = 1, 2, \dots\}$ and $\{Y_{rj}; j = 1, 2, \dots\}$, ($r = 0, 1, 2, \dots$) are mutually independent. Following the procedure as given in Suchindran¹⁴, the Laplace transforms, say, $\phi_0(s)$ and $\phi_r(s)$ of T_0 and T_r ($r \geq 1$) respectively are obtained as:

$$\phi_0(s) = \frac{m_0(c_0 + s) \theta_0}{s^2 + (m_0 + c_0)s + m_0 c_0 \theta_0} \quad (5)$$

and

$$\phi_r(s) = \frac{m_r(c_r + s) \theta_r}{s^2 + (m_r + c_r)s + m_r c_r \theta_r} e^{-sh} , \quad r > 0 \quad (6)$$

Since $T_0, T_1, T_2, \dots$ are mutually independent the Laplace transform of Z_{r+1} , $\Psi_{r+1}(s)$ (say), is

$$\begin{aligned}\Psi_{r+1}(s) &= \prod_{i=0}^r \phi_i(s) \\ &= \left[\prod_{j=0}^r m_j \theta_j \right] \prod_{j=0}^r (c_j + s) e^{-srh} \prod_{j=0}^r \{ s^2 + (m_j + c_j)s + m_j c_j \theta_j \} \\ &= \left\{ \prod_{j=0}^r m_j \theta_j \right\} \left\{ \frac{U^{(r+1)}(s)}{V^{(r+1)}(s)} \right\} e^{-srh} \quad (7)\end{aligned}$$

$U^{(r+1)}(s)$ is a polynomial of degree $r+1$ in s ;

$$U^{(r+1)}(s) = \sum_{j=0}^{(r+1)} l_{(r+1-j)} s^j$$

$$l_0^{(r+1)} = 1; \quad l_j^{(r+1)} = \sum_{i_1, i_2, \dots, i_j=0}^r c_{i_1} c_{i_2} \dots c_{i_j};$$

$$i_1 < i_2 < \dots < i_j$$

and

$$V^{(r+1)}(s) = \prod_{j=0}^r (s + v'_{2j}) (s + v'_{2j+1})$$

v'_{2j} and v'_{2j+1} are the negative of the roots of the equation $s^2 + (m_j + c_j)s + m_j c_j \theta_j = 0$ and both v'_{2j} v'_{2j+1} are greater than zero.

Let us assume that among the $2(r+1)$ values $v'_0, v'_1, \dots, v'_{2r+1}$, k are distinct and we denote them by $v_1, v_2, \dots, v_k$ and let n_i is the number of v' 's which are equal to v_i such

that $\sum_{i=1}^k n_i = 2(r+1)$. Then

$$\Psi_{r+1}(s) = \left[\left\{ \prod_{j=0}^r m_j \theta_j \right\} \left\{ u^{(r+1)}(s) / \prod_{i=1}^k (s+v_i)^{n_i} \right\} \right] e^{-srh} \quad (8)$$

Now, the bracketed term in (8) can be written as

$$\sum_{i=1}^k \sum_{j=1}^{n_i} A_{ij} v_i^j (s+v_i)^{-j} \quad (9)$$

where

$$A_{i, n_i - j} = \frac{\prod_{j=0}^r m_j \theta_j}{v_i^{n_i - j} j!} \frac{d^j}{ds^j} \left[\frac{u^{(r+1)}(s)}{v_i^{(r+1)}(s)} \right]_{s=-v_i} \\ j=0, 1, \dots, n_i-1.$$

$$= \left\{ \prod_{j=0}^r m_j \theta_j \right\} D_{ij} / v_i^{n_i - j} j!$$

$$v_i^{(r+1)}(s) = \prod_{\substack{j=1 \\ j \neq i}}^k (s + v_j)^{n_j},$$

$$D_{i,0} = u^{(r+1)}(-v_i) / v_i^{(r+1)}(-v_i) \quad \text{and}$$

$$D_{i,j} = \frac{1}{v_i^{(r+1)}(-v_i)} \left[\left\{ \frac{d^j}{ds^j} u^{(r+1)}(s) \right\} \right]_{s=-v_i}$$

$$- \sum_{l=1}^j \binom{j}{l} D_i^{(j-l)} \left\{ \frac{d}{ds} \frac{v_i^{(r+1)}(s)}{l} \right\} \Big|_{s = -v_i}$$

The inverse of (9) is

$$\sum_{i=1}^k \sum_{j=1}^{n_i} A_{ij} \left[1 - e^{-v_i t} \sum_{u=0}^{j-1} \frac{(v_i t)^u}{u!} \right] \quad (10)$$

If $H_{r+1}(t)$ is the inverse of (8) then

$$H_{r+1}(t) = \sum_{i=1}^k \sum_{j=1}^{n_i} A_{ij} \left[1 - e^{-v_i(t-rh)} \sum_{u=0}^{j-1} \frac{\{v_i(t-rh)\}^u}{u!} \right] \quad \left. \begin{array}{l} \text{for } t > rh \\ (11) \end{array} \right\}$$

$= 0$, otherwise.

Since $a_0 a_1 \dots a_r$ is the probability that female will not acquire sterility upto the occurrence of the r^{th} live birth, the probability that the female will have at least $(r+1)$ live births during $(0, T)$ is

$$H_{r+1}^*(T) = a_0 a_1 \dots a_r H_{r+1}(T-g),$$

where g is the length of the gestation period for a live birth.

The probability of exactly r live births during $(0, T)$ is

$$P[X(T) = r] = H_r^*(T) - H_{r+1}^*(T), \quad r = 0, 1, 2, \dots, n-1$$

$$P[X(T) = n] = H_n^*(T)$$

where $H_0^*(T) = 1$, and $n = \left[(T-g)/h \right] + 1$ and $\left[(T-g)/h \right]$ stands for the greatest integer not exceeding $(T-g)/h$.

Illustration

A programme has been developed in HI BASIC language for a DCM Spectrum 7 micro-computer to obtain the numerical value of the probability expressions for given numerical values of the parameters. For the purpose of illustration, consider a woman with parameters (which do not depend on marriage duration or parity): risk of conception, 0.6; probability that a conception resulting in a spontaneous abortion, 0.25; non-susceptible period of constant duration associated with a live birth, 1.25 years (0.75 year of gestation and 0.5 year of P.P.A.) and the variable duration of non-susceptible period associated with a foetal wastage follows an exponential distribution with parameter $1/C_i = 0.5$ year ($i = 0, 1, 2, \dots$). Table 1 shows the probabilities of different order of births to the woman in the period of 15 years.

The model is used as follows to show, the expected change in fertility when the woman uses contraceptives of varying effectiveness, may undergo for medical termination of pregnancy (MTP) and may adopt sterilisation depending on parity as follows:

1. Use of contraceptives

A_0 : no contraceptive, i.e., $m_i = 0.60$ for $i = 0, 1, \dots$

A_1 : 40 per cent effectiveness following first live birth ($m_0 = 0.60$, $m_i = 0.36$, $i = 1, 2, \dots$).

A_2 : 40 per cent effectiveness between parities 1 and 3 and 80 per cent effectiveness thereafter ($m_0 = 0.60$, $m_1 = m_2 = 0.36$, $m_i = 0.12$, $i = 3, 4, \dots$)

TABLE 1
THE PROBABILITY OF EXACTLY X BIRTHS IN A PERIOD OF FIFTEEN YEARS

No. of births	0	1	2	3	4	5	6	7	8+
Probabilities	0.003	0.026	0.105	0.227	0.289	0.222	0.100	0.025	0.003

Average 4.0

2. *Chance for undergoing an induced abortion*

B_0 = no provision for induced abortion, i.e. , $\theta_i = 0.75$ for $i = 0, 1, 2, \dots$

B_1 = zero until third live birth and 25 per cent thereafter. ($\theta_0 = \theta_1 = \theta_2 = 0.75$, $\theta_i = 0.5625$, $i = 3, 4, \dots$)

B_2 = zero until third live birth and 50 per cent thereafter ($\theta_0 = \theta_1 = \theta_2 = 0.75$, $\theta_i = 0.375$, $i = 3, 4, \dots$)

3. *Chance for undergoing sterilisation*

C_0 = no provision for sterilisation, i.e. $a_i = 1$ for $i = 0, 1, 2$

C_1 = zero until the second live birth and thereafter 40 per cent following each child birth ($a_0 = a_1 = a_2 = 1$, $a_i = 0.60$, $i \geq 3$).

C_2 = zero until the second live birth and thereafter 80 per cent following each child birth ($a_0 = a_1 = a_2 = 1$, $a_i = 0.20$, $i \geq 3$).

C_3 = zero until the third live birth and thereafter 40 per cent following each child birth ($a_0 = a_1 = a_2 = a_3 = 1$, $a_i = 0.60$, $i \geq 4$).

C_4 = zero until the third live birth and thereafter 80 per cent following each child birth ($a_0 = a_1 = a_2 = a_3 = 1$, $a_i = 0.20$, $i \geq 4$).

Thus, the programme $A_1 B_1 C_2$ means that a woman uses a contraceptive of 40 per cent effectiveness after first parity, may go for an induced abortion with probability 0.25 and may adopt sterilisation following third and each subsequent child birth with probability 0.80. The reduction in family size and probabilities for different order of births in first fifteen years of marriage are shown in Table 2.

A homogeneous group of women would give birth to four children in first fifteen years (Table 1) in the absence of any family planning method. A reduction in births of 22 per cent can be achieved through the programme A_1 , about 13 per cent through B_2 and 25 per cent through C_2 . It is about 30

TABLE 2

PROBABILITIES OF EXACTLY X BIRTHS IN A PERIOD OF FIFTEEN YEARS AND
PERCENTAGE REDUCTION IN BIRTHS UNDER DIFFERENT PROGRAMMES

Programmes	Number of Births					Average	Percentage reduction in births
	0-1	2	3	4	5 or more		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
$A_0 B_0 C_1$	.03	.10	.48	.26	.13	3.3	16
$A_0 B_0 C_2$	.03	.10	.74	.12	.01	3.0	25
$A_0 B_0 C_3$	.03	.10	.23	.43	.21	3.7	7
$A_0 B_0 C_4$	.03	.10	.23	.57	.07	3.5	11
$A_0 B_1 C_0$	.03	.10	.30	.32	.25	3.7	6
$A_0 B_1 C_1$	.03	.10	.53	.25	.09	3.3	18
$A_0 B_1 C_2$	.03	.10	.75	.10	.01	3.0	26
$A_0 B_1 C_3$	.03	.10	.30	.42	.15	3.5	11
$A_0 B_1 C_4$	.03	.10	.30	.52	.05	3.4	13
$A_0 B_2 C_0$	.03	.10	.41	.31	.15	3.5	13
$A_0 B_2 C_1$	.03	.10	.59	.22	.06	3.2	21
$A_0 B_2 C_2$	.03	.10	.77	.09	.01	2.9	26
$A_0 B_2 C_3$	.03	.10	.41	.37	.09	3.4	15
$A_0 B_2 C_4$	.03	.10	.41	.43	.03	3.3	17
$A_1 B_0 C_0$	.09	.24	.32	.23	.12	3.1	22
$A_1 B_0 C_1$	.09	.24	.47	.16	.04	2.8	29
$A_1 B_0 C_2$	.09	.24	.60	.06	.01	2.7	33
$A_1 B_0 C_3$	.09	.24	.32	.28	.07	2.0	24
$A_1 B_0 C_4$	.09	.24	.32	.33	.02	3.0	25
$A_1 B_1 C_0$	.09	.24	.37	.22	.08	3.0	25
$A_1 B_1 C_1$	.09	.24	.49	.15	.03	2.8	30
$A_1 B_1 C_2$	.09	.24	.61	.06	*	2.7	33
$A_1 B_1 C_3$	.09	.24	.37	.25	.05	2.9	26

Contd.....

(Table 2 Contd.)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
$A_1B_1C_4$	.09	.24	.37	.28	.02	2.9	27
$A_1B_2C_0$	.09	.24	.45	.18	.04	2.9	28
$A_1B_2C_1$	.09	.24	.54	.12	.01	2.7	31
$A_1B_2C_2$	.09	.24	.63	.04	*	2.6	34
$A_1B_2C_3$	.09	.24	.45	.20	.02	2.8	29
$A_1B_2C_4$	.09	.24	.45	.21	.01	2.8	29
$A_2B_0C_0$	.09	.24	.50	.15	.02	2.8	30
$A_2B_0C_1$	.09	.24	.56	.10	.01	2.7	32
$A_2B_0C_2$	.09	.24	.64	.03	*	2.6	34
$A_2B_0C_3$	.09	.24	.50	.16	.01	2.8	30
$A_2B_0C_4$	.09	.24	.50	.17	*	2.8	30
$A_2B_1C_0$	.09	.24	.54	.12	.01	2.7	31
$A_2B_1C_1$	.09	.24	.59	.07	.01	2.7	33
$A_2B_1C_2$	.09	.24	.65	.02	*	2.6	34
$A_2B_1C_3$	.09	.24	.53	.13	.01	2.7	31
$A_2B_1C_4$	.09	.24	.53	.14	*	2.7	31
$A_2B_2C_0$	.09	.24	.57	.09	.01	2.7	32
$A_2B_2C_1$	.09	.24	.62	.05	*	2.7	33
$A_2B_2C_2$	.09	.24	.65	.02	*	2.6	35
$A_2B_2C_3$	.09	.24	.58	.09	*	2.7	32
$A_2B_2C_4$	.09	.24	.58	.09	*	2.7	33

*indicates that probability is less than 0.005.

per cent with A_2 and a further reduction of only 2 to 5 per cent can be achieved by combining B_2 or C_2 or both with A_2 whereas the above combination with A_i would give a higher reduction. This is obvious because higher the effectiveness of the contraceptives practised since 3rd birth, the longer would be the intervals and consequently smaller would be the number of pregnancies after third birth and births of order four or more.

सारांश

इस लेख में गर्भधारण दर, भ्रूण क्षरण घटनाओं तथा जन्मक्रम के आधार पर एक बच्चे के जन्म के पश्चात अप्रजननशीलता की प्रक्रिया प्रारम्भ हो जाने की घटनाओं को आधार मान कर एक निर्धारित समयान्तराल $(0, T)$ की T लम्बाई की अवधि में एक महिला द्वारा, उसके विवाह के समय से लेकर, दिये गये जन्मों की संख्या की गणना हेतु एक माडल प्रस्तुत किया गया है तथा गर्भधारण के प्रतिमानों में हो रहे परिवर्तनों के संदर्भ में परिवार नियोजन कार्यक्रमों का मूल्यांकन करने के लिए इस माडल को प्रयोग में लाने का ढंग दर्शाया गया है। इस माडल को प्रयोग में लाने का तरीका विभिन्न उदाहरण देकर भी समझाया गया है।

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INTERNAL TRANSPORTATION OF SUPPLIES IN HOSPITALS

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ABSTRACT

Hospitals are the most costly part of the health care service budget. Hence it is sound economics, to do everything feasible to minimise hospital expenditure. Also, if there is no sound and efficient system of internal transportation of supplies like drugs, linen, equipment, and food etc. to the patients, howsoever efficient and competent technical and administrative staff may be there, the standard of patient care will be at low ebb with poor patient and community satisfaction.

Modern hospitals require efficient methods of transporting a wide variety of items because of multifarious activities which are required for the patient care located at considerable distance and at different places. To meet this requirement a range of systems have been developed like pneumatic tubes system, automatic trolley system, tray conveyors and automatic dumb waiter system. The requirement of a particular type of transportation system- will depend upon the needs, type, location and architectural peculiarities of the hospital. A modern hospital manager has to be conversant and knowledgeable about these methods for bringing about efficiency and effectiveness of these in the hospital.

An attempt has been made to highlight the various types of modern internal transportation systems and their importance.

Transportation in every organisation plays an important role in connecting activities taking place at different loca-

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tions. Its importance is profoundly felt in a hospital setting because the multifarious activities required for patient care have to be located at variable distances- from each other. It is the transportation system which unites these activities so as to achieve the objective of good patient care.

Ejerhed defined hospital transport as "movement of persons or goods as an integral ancillary service system in the unity of the hospital". Hospital transportation is of two types (a) extramural or external transportation (from outside to the hospital) and (b) intramural or internal transportation (within the hospital). Circulation space within and between departments take 20 to 25 per cent of the area of the hospital and it is estimated that 10 per cent of the investment cost goes towards the transport. Of the total time spent on transportation in a hospital 1/3rd is spent on movement and 2/3rds on waiting.

Peckham stated that circulation, traffic and transportation are most important factors which influence the basic concept of planning because of its involvement with the inter-relationship of all departments within the hospital.

Modalities

It has been advocated that parts of hospital that are most closely linked to the community should be allotted positions closest to the main entrance to the site. These include the out-patient and casualty services and other facilities needed to provide a base for domiciliary services.

Next in order of distance from the entrance should be a Zone allotted to the medical service department that is Radio-Diagnosis and Laboratories. Next should be the area earmarked for inpatient care. Apart from these, substantial area is required for the house-keeping and domestic services - stores, laundry, kitchen and boiler house to which most of the delivery vehicles go. This service area should be independent of and can be remote from the main hospital entrance. Staff housing, which will take up a substantial proportion of the site, can best be placed around the perimeter to give easy access to the staff with the outside world.

The Ministry of Health Bulletin titled "Traffic Movement and the Inter-relationship of the Department" (1969) has utilised the following three factors for evaluation of the traffic pattern:

a. *Frequency and Type*

This refers to journeys made by people, out-patients, medical staff, paramedical staff, other staff and visitors. It also refer to movement of goods and vehicles.

b. *Bulk*

This refers to movement of goods by mechanical means or manual.

c. *Urgency*

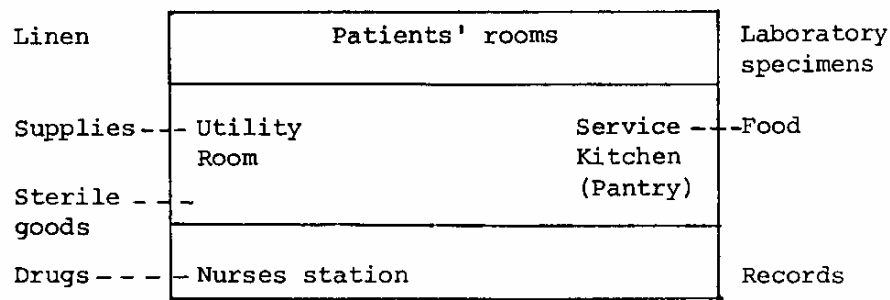
Which implies preferential needs.

Based on above factors the following departments should be located in relation to each other: (i) Outpatient department, (ii) Emergency department, (iii) Outside hospital entrance, (iv) X-ray department, (v) Laboratory, (vi) Surgical suite, (vii) Medical records, (viii) Pharmacy, (ix) Maintenance shops, and (x) Administrative Offices.

Peckham suggested that all the above departments should be located at one level so as to permit shortest and quickest means to get from one department to another.

Transportation of supplies to and from the central sterilisation and supply department. Central Storage, Laundry, Centralised Hospital Equipment, the Dietary Department and the Pharmacy creates bulk traffic.

Showing flow of goods to patients



These departments which created bulk traffic, should therefore, be planned and located in a centralised location around the despatch and return centre. This will be a vital planning factor in creating an overall hospital design.

Inter-Departmental Traffic

The three main hospital areas .namely, inpatient, outpatient and treatment areas should be planned in such a way so as to preserve as far as possible the separation of the inpatient and outpatient traffic and to provide for the efficient movement of supplies and services throughout the hospital. The outpatient .traffic should not be allowed to mix with inpatient and other hospital traffic.

Circulation Patterns and Design

Delruce stated that morphologically complex buildings can be classified according to the following four different circulation patterns with increasing expansion possibilities.

1. *Radial Circulation*

It is self-restricting simply because it establishes a centre and tends to limit the expansion of a building.

2. *Linear Circulation*

It is a pattern where expansion is confined to the two open ends of the circulation route. Growth on the level of a complete department will mean addition of new length of building to one of the two open ends.

3. *Dentritic Circulation*

It is basically linear with main branch routes. This pattern leads itself to irregular shape of building and has a fair number of growth possibilities. Distance between various departments may become very long.

4. *Grid Circulation*

It is open ended and have the following advantages: (i) grids can grow in any direction, independent of the departmental growth. The new growth is served by the main circulation grid; (ii) grids make possible a greater range of association between departments and parts of building complex, and (iii) grids provide a higher degree of accessibility than what is possible in any other circulation pattern.

Designs in Developing Countries

Due to frequent breakdowns or interruptions in the electricity supply, there is need for paying special attention to the reliability of the whole traffic system in the developing countries. Horizontal corridors, easy ramps and additional staircases should be provided as these are the most reliable. It has been recognised that use of elevators is highly disturbing for uninformed people in developing countries.

Parking Spaces

Wheeler suggested the following parking spaces:

Area required - one acre for 140 cars

Inpatient - 1 to 2 spaces per bed

Outpatient - 4 to 6 spaces for each doctor

Parking area should be located atleast 30 feet from the main building. Doctor's parking should be near the main staff entrance and the visitors parking should be near the main entrance.

Entrance and Ramps: All entrances and ramps should be wide enough to permit passage of stretchers and wheel chairs.

Exit Stairways: Exit stairways should be located at the end of each corridor to preclude dead ends where occupants may be trapped in fire and other disasters. The staircase should be 4'-6" wide to permit the patients being carried. However, the fire escape stair could be 3'-6" wide and with 4'-6" width at the main landing.

Corridors: All corridors should be wide enough to permit easy passage of two hospital beds. Width of corridors should be 8 feet.

Doors: According to McGibony, the door should be wide enough to permit the entrance of an occupied hospital bed and should not be less than 3'-10".

Flooring: For the heavy traffic encountered in the central generator store, at the receiving point in the boiler room, laundry and other storage space, concrete floor with hardened surface should be provided.

Transportation Methods

Internal Transportation System

Before a new system is introduced, the existing system should be studied to find out types of goods transported, method of transport, grade of staff involved and time taken in transport.

The information on the volume and quantities of goods and of the times at which they have to be transported is important for determining the layout of the system, speed, container, size, conveyor line and lift requirements. Important indices which can be derived from material flow analysis are: (a) total transport volume per patient per day; (b) transport time per patient per day; and (c) volume of transport by nurses per patient per day.

- a. Automatic Transportation System: Owing to increased personnel cost and the non-availability of personnel for manual method of transportation in the western world, the hospital internal transportation system is being increasingly automised. Hospital progress[^] indicated the following advantages of automation:
 - i. Reduction in Nursing Staff.
 - ii. Improved service.
 - iii. Saving of time in moving drugs, supplies etc.
 - iv. 24 hour operation.

- v. Release of nursing staff to do other duties,
- vi. Improved hygiene.
- b. *Electric Vehicles*: Moore pointed out that Crompton Electricals have developed electric vehicles which can perform duties in a hospital at a controlled speed of (12 mph) and also can run at higher speeds. The vehicle battery and charger form a simple and efficient transport machine, reliable through its simplicity.
- c. *Cabin Lift*: It is an overhead suspended transport system which can carry 12 persons or 1000 kg. which is an electrically driven and automatically controlled system. The programmed speed is 20 to 30 km per hour reducing towards the end of the run to 3 to 4 km per hour.
- d. *Pneumatic Tube System*: This system is used for transporting requisitions, prescriptions, medications, X-ray, specimen, instruments medical records, charge slip, menus, correspondence, work requests and emergency materials. This system can be either carrier or station controlled.
- e. *Rally Post*: This system comprises three components:
 - i. Track - consists of a rail with a gauge of 22 cm;
 - ii. Electric Motors - Runs along the rails and is directed by Magnets which work to a code. It can run for 5 hours in each charging; and
 - iii. The containers - made of light metal or plastic these can take a load of upto 5 kgs. With maximum load the speed is 0.6 km per second. The containers can carry items like mail, cash, punched cards and fluids.

The rally post system can be installed in existing buildings as well as in new ones.

- f. *3 D Batin*: This is a three dimensional car conveyors by which metal boxes are moved along toothed track on noise- less plastic wheels. The boxes are retained in a central depot. Movement of the system is automatic under the control of a central programming office. The boxes return to the

depot by the shortest route. Doors separating the conveyor from the destination point open automatically on arrival of a box. Collision and accidents are impossible in this system.

Transportation Costs

Meister stated that studies in a university hospital revealed that for every 100 patients six members of staff are required, each spending eight hours of work a day on transportation alone.

In a well organised Modern Hospital $\frac{3}{4}$ of the cost of transport goes on staff pay, which rises all the time and $\frac{1}{4}$ on the capital cost which remains relatively stable.

Comparisons of Various Transportation Systems

The following systems were subjected to an economic and operational evaluation. It was found that integrated supplies service would be more efficient than separate departmental service.

- a. Porter and Messenger Service
- b. Tug/Trolley and Messenger Service
- c. Automatic Tug System
- d. Overhead Monorail System

Porter and messenger service was found to be comparatively cheap to install, but expensive to operate and may be difficult to be fully manned.

The manual portering services when replaced by battery operated tug was expensive to operate though requiring less labour force than the porter and messenger service.

Of the two automatic systems the automatic tug system was preferred to overhead monorail as the supply centre fully controlled delivery and collection.

Hospital Insurance Survey after making a comparative study of various transportation systems pointed out that the evidence clearly indicates that fully automatic system for hospitals at this stage of their development cannot be justified on the basis of anticipated savings in labour costs.

Transportation and Infection

Three types of contamination with micro-organisms are distinguished: (a) contamination of transported goods; (b) contamination of the wrappings; and (c) contamination of transport containers.

Contamination during transport can result from: (a) contact or droplet infection from the shaft while loading and unloading; (b) particles dispersed from infected material; (c) airborne particles on transport routes and at the loading and unloading points; (d) contact with floors, wall or other conveyors; and (e) from vermin.

It is, therefore, recommended that: (a) all sterile goods must be transported in sealed containers; (b) to ensure regular and thorough cleaning of conveyors, containers and tracks; (c) care must be taken to prevent contamination during loading, unloading and when goods are taken to the point of use; and (d) ducts and chutes, which present contamination risks, should not be used for transporting wastes.

Hospital Elevators (Lifts)

Hospital both in developed and developing countries to a large extent depend on elevators (lifts) for their transportation system. The hospital lifts should be big enough to accommodate a hospital bed.

Indian Standard Institute (ISI) has defined hospital lift as a lift normally installed in a hospital/dispensary/ clinic and designed to accommodate one number bed/stretcher along its depth, with sufficient space around to carry a minimum of three attendants in addition to the lift operator.

McCaulay suggested that to use lifts economically and efficiently it would be advisable to concentrate the lifts instead of distributing them to different parts of the building. Four lifts banked together will have the same service as eight individual lifts distributed at separate points.

All lifts should be provided with floor and direction indicators so that persons waiting for lifts are able to see

where the cab is and which way it is going. Electric service to lifts should be arranged in such a way that atleast one of the lifts hospital type, may be operated on the emergency system.

Indian Standard Institute has described the dimensions for lifts as under:

DIMENSIONS FOR HOSPITAL LIFTS

Capacity		Speed (Feet per Minute)	Dimensions		
Persons	Lbs		Entrance	Breadth	Length
15	2246	300	32	38"	96"
20	2995	300	48	52"	96"
26	3893	300	48	64"	96"

DIMENSIONS FOR SERVICE LIFTS

Speed	Entrance	Breadth	Depth	Height
120	28"	28"	28"	32"
120	32"	32"	32"	36"
120	36"	36"	36"	40"
120	40"	40"	40"	48"

Distribution System

WHO Expert Committee (Report TRS No.395.68) recommended that supply system in hospitals should be modernised, supplies should be delivered by the supplying services rather than picked up from them by departments.

A. Drugs

The following systems of dispensing for inpatient are in use:

1. Complete floor pack system
2. Individual prescription order system
3. Unit dose packing and unit dose dispensing

1. Complete Floor Pack System

In this system the nurse maintains a stock of commonly used drugs in the nursing station cupboard and replenishes her stock periodically by placing requisitions on medical stores. In this system, the nurse has to spend considerable part of her time on indents, storage and accounting and secondly the system involves risks like error in physicians order, error in interpretation of doctors order by the nurse etc.

For conveyance of drugs from store in nursing floor, two methods are used.

- a. **Drug Basket System:** In this system the nurse despatches the drug basket containing a set of containers, alongwith the requisition forms to the store which fills up the requisition and the basket is returned to the nursing station.
- b. **Topping-up System:** In this system the pharmacist with the ward in a mobile van filled with drugs goes around. He checks the inventory of drugs, prepares the requisition in duplicate, leaves one copy with nurse and retains the other copy with the pharmacy. This system has the following advantages: (i) it saves nurse's time; (ii) it prevents hoarding and deterioration of drugs at the nursing station; and (iii) it develops rapport between pharmacist and the nursing staff (Hospital O and M service report, 1966).

2. Individual Prescription Order System

In this system the doctor writes the prescription on the doctor's order form, the nurse copies it on a drug order form and sends it to the pharmacy and the pharmacist dispenses the drugs on the basis of average length of stay in the hospital. The disadvantages of this system are: (i) an error on the part of nursing staff to interpret and transcribe doctor's prescription; and (ii) medication of patient may change at any moment resulting in return of unused drugs to the pharmacy, and thereby imposing additional accounting problems in pharmacy.

By introducing stop order system prescription orders are automatically stopped when a specific period has elapsed unless a new prescription is written. Another useful method is to prepack four days quantity at the end of which the nurse must speak to the doctor and request a new order for a new supply of medication¹⁴.

3. Unit Dose Packing and Unit Dose Dispensing

Unit dose packing means enclosing a single dose of medication with in a single compartment, each compartment having a label as regards identity of drugs and its dose. Miller reported considerable reduction in medication errors by this system.

B. Sterile Supplies

Hughes pointed out that distribution of packs has been identified as the responsibility of the CSSD. The essential principles of distribution are: (a) avoid overstocking and loading in the ward; and (b) avoid stock out through emergency supplies. To satisfy these conditions the following systems have been advocated.

1. The one for one system: By this system a load of standard composition is delivered daily to each ward and unused stock from the previous days issue is returned. Used articles are collected separately.
2. The Milk-round system: In this the daily topping up of each ward stock is done to an agreed level.
3. The Grocery system: In this wards send their requisition to CSSD, which makes deliveries in accordance with demand.
4. The 'clean for dirty exchange' system: Under this system one clean article is issued for each dirty one returned to the CSSD.

C. Linen:

According to O and M work study survey, 1972 different types of linen distribution systems- are: (1) Exchange Trolley System - In this system approximate requirement for a given

number of days is calculated at a pre-determined rate and despatched to the ward without requisition; (2) Topping up System; (3) Requisition System - This system is basically a means of communicating the requirement of wards/departments to the laundry in writing; and (4) Daily Quota System - This system is similar to number (1) given above, in that a day's requirement is issued directly from the central linen room.

D. Food

McGibony suggested that food services of patients are generally of two types:

1. Centralised Service - In this system, the food is prepared in a central kitchen and trays are sent to all patient floors from a central serving unit.
2. Decentralised Service - In this service the food is prepared in central kitchen and then sent in back to the floors where it is apportioned on trays and served to the patients.

The hospital planners should plan to make available one elevator exclusively for distribution during the meal service periods, for a given and efficient food distribution system.

Total Supply by Cost Exchange

This system of distribution is preferred to the automated system because of its greater flexibility and lower cost.

In this system, two mobile trolleys for one ward are used. These are filled with all the supplies needed by the ward and supplied to the nursing units. This system relieved the nursing staff of non-nursing tasks and incorporated an effective way of billing the patient.

Lkkjk'k

अस्पताल स्वास्थ्य देखरेख सेवाओं संबंधी बजट का सबसे खर्चीला भाग है। अतः ठोस अर्थ व्यवस्था ही ऐसा पहलू है जिसके आधार पर अस्पताल व्यय को कम से कम रखने के लिए हर संभव प्रयास किये जा सकते हैं। इसके साथ-साथ यदि रोगियों को औषधि, क्षौमवस्त्र, उपकरण तथा खाना बांटने आदि

संबंधी आन्तरिक व्यवस्था ठोस एवं सक्षम नहीं होती है तो चाहे तकनीकी एवं प्रशासनिक स्टाफ कितना भी कुशल एवं सक्षम क्यों न हो गरीब रोगियों को उपलब्ध स्वास्थ्य देखरेख तथा सेवाओं के प्रति समुदाय का सन्तुष्टि स्तर बहुत निम्न श्रेणी का होगा।

इस लेख के माध्यम से अस्पतालों में विभिन्न प्रकार की आधुनिक आन्तरिक प्रणालियों तथा उनके महत्व पर प्रभाव डालने का प्रयास किया गया है।

आधुनिक अस्पतालों की बहुमुखी गतिविधियों को ध्यान में रखते हुए, जो दूरस्थ तथा विभिन्न स्थानों पर स्थिति रोगियों की स्वास्थ्य देखरेख प्रदान करने हेतु आवश्यक होती हैं, विस्तृत स्तर पर विविध प्रकार की मदों के परिचालन हेतु कुशल तरीकों का होना आवश्यक है। इस आवश्यकता को पूरा करने हेतु अनेक प्रकार के तरीके प्रचलित हैं, जैसे वायवीय ट्यूब सिस्टम, स्वचालित ट्राली सिस्टम, ट्रे कन्वेयरस सिस्टम तथा आटोमेटिक डम्ब वेटर सिस्टम।

किस स्थान पर परिचालन की कौन सी प्रणाली विशेष की आवश्यकता होगी यह अस्पताल की आवश्यकताओं, प्रकार, स्थानीय स्थिति तथा अस्पताल के निर्माण संबंधी ढांचे पर निर्भर करता है। एक आधुनिक अस्पताल प्रबन्धक के लिए अपने अस्पताल में इस प्रकार की कुशलता तथा प्रभावकारिता लाने हेतु उसे इन तरीकों से परिचित होना आवश्यक है तथा इनके बारे में उसे ज्ञान होना चाहिए।

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AN EVALUATION OF MATERNAL CARE SERVICES IN A SEMI-URBAN
COMMUNITY OF PONDICHERRY

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ABSTRACT

A cohort of 102 women who experienced more than one pregnancy during a defined period was studied to assess the changing trend in their utilisation of the maternal care services provided by the Urban Health Centre Pondicherry. The findings have also been compared with those reported in a similar study earlier.

There has been a considerable development in the provision of maternal and child health services in our country during the last decade. These are, now, being provided alongwith family welfare services as a 'Health Care Package' through the various health centres - both in the urban and in the rural areas. The performance of these health centres in the delivery of maternal care services as well as the utilisation by the target population of the services provided need to be assessed but have been the subject of only a few studies.

Srinivasa et al.\$ (1977) had attempted an assessment of the quality of maternal care services provided by an Urban Health Centre of Pondicherry by studying the changing trend in the utilisation of these among a cohort of mothers, who experienced more than one pregnancy, during a five year period.

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Objectives

This study was undertaken (i) to assess qualitatively the maternal care services provided by the health centre at present and (ii) to determine the improvement, if any, in the utilisation after an interval of four years since the previous study.

Material and Methods

The study was conducted at the Urban Health Centre attached to the Department of Preventive and Social Medicine, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, during a four years' period from 1st January, 1978 to 31st December, 1981. Comprehensive family centered community health services are provided by this centre to a population of 7,065 (1978 enumeration), residing in an area of one square kilometre. The staff: population ratio is one doctor for approximately 7,000 population and one Public Health Nurse and one Midwife for nearly 3,500 population. The system of maintenance of family folders and other MCH records and registration of vital events have already been reported.

The maternal care covers registration of pregnancies, periodic antenatal examinations, tetanus toxoid immunisation, attending or supervising home deliveries, referral of high risk mothers and post-natal care.

During the study period, among 919 eligible couples, there were 656 pregnancies. Of these, 102 women who experienced more than one pregnancy and delivery during this period were taken as the cohort. Thus, there were 102 pregnancies occurring for the first time during the study period, hereinafter referred to as earlier pregnancies, 96 of these women had one subsequent pregnancy each while the rest six had two subsequent pregnancies each during the period of study, thus giving a total of 108 subsequent pregnancies.

The factors considered for assessing the extent of utilisation of maternal care services were: (i) time of commencement of antenatal care; (ii) frequency of antenatal clinic visits; (iii) immunisation with tetanus toxoid; and (iv) place of delivery and, in case of domiciliary delivery, the person conducting it.

Results

The age and parity of the cohort at the time of their earlier pregnancy and their religion are given in Table 1.

Age: The majority of 58 per cent of the women were in the age group of 15 to 24 years. Those aged 35 and above constituted only 5 per cent.

Parity: Women of parity orders two to four formed 48 per cent of the cohort and 34.3 per cent were primi-parous as against 17.7 per cent who were of parity orders five and above.

Religion: Religion-wise, the cohort was found to be similar to the general group of pregnant women of which Hindus constituted 87 per cent of majority.

The socio-economic characteristics of the cohort are shown in Table 2.

TABLE 1
AGE, PARITY AND RELIGION OF THE COHORT (N>102)

Characteristic		Percentage
1.	Age group (in years)*	
	15-24	57.8
	25-34	37.2
	35 and above	4.9
2.	Parity*	
	One	34.3
	Two	22.6
	Three	15.7
	Four	9.8
	Five and above	17.7
3.	Religion	
	Hindu	87.3
	Christian	11.8
	Kualin	1.0

*at the time of earlier pregnancy

TABLE 2
SOCIO-ECONOMIC CHARACTERISTICS OF THE COHORT (N=102)

Characteristics	Percentage
1. Educational Status:	
i. Illiterate	45.1
ii. Literate	54.9
Primary	30.4
Middle School	17.7
High School	6.9
2. Educational Status of the Husbands:	
i. Illiterate	15.7
ii. Literate	84.3
Primary	31.4
Middle School	33.3
High School	17.6
College	2.0
3. Occupational Status:	
Housewife	89.2
Labourer	2.9
Vendor	7.8
4. Occupational Status of the Husbands:	
Unskilled worker	47.1
Skilled worker	31.4
Shop-keeper	16.7
Fisherman	4.9
Pensioner	2.0
5. Family Income (in Rs./month)	
Upto 100	2.0
101-200	29.4
201-300	33.3
301-400	18.6
401-500	11.8
501 and above	4.9

Literacy Status: Among the cohort, 55 per cent were literate. Of the literate women, 62.5 per cent had education of middle or high school level. Eighty six per cent of the spouses of the women were literate and of these, 62.8 per cent had education above primary level.

Occupational Status: Only 11 per cent of the women were working, the rest 89 per cent being housewives. Amongst their spouses, except for 2 per cent who were pensioners, the rest skilled and unskilled workers were all gainfully occupied and constituting 78.5 per cent of majority.

Family Income: Only 31.4 per cent of the cohort had a family income of Rs.200 or less per month.

Utilisation of Maternal Care Services

Registration of Pregnancy: When the time of commencement of antenatal care was compared between the earlier pregnancies of the cohort and their subsequent ones; the proportion of women, registering in the first trimester itself, showed a 1.5 fold increase in their subsequent pregnancies and 39.8 per cent when compared with their earlier pregnancies which were 26.5 per cent. Only a marginal difference was found among those registering after 24 weeks of pregnancy. These differences, however, were not significant statistically and are given in Table 3.

TABLE 3

TIME OF REGISTRATION DURING EARLIER AND SUBSEQUENT PREGNANCIES OF THE COHORT

Duration of Pregnancy in Weeks at Time of Registration	Earlier Number	Pregnancy Percentage	Subsequent Number	Pregnancy Percentage
Uptp 12	27	26.47	43	39.81
13-24	60	58.82	47	43.52
25-32	11	10.78	12	11.11
33 and Above	4	3.92	6	5.56
Total	102	100.00	108	100.00

$X^2 = 5.5278$ d.f.= 3 $p > 0.1$ Not significant

Antenatal Clinic Visits-. The number of visits paid by the cohort during their earlier and subsequent pregnancies to the antenatal clinic is given in Table 4. The proportion of the cohort attending the clinic three or more times was observed to be almost equal. As against 20.6 per cent of the cohort who had not attended the clinic at all for their earlier pregnancies, only 11.1 per cent of the women absented themselves from the clinic during their subsequent pregnancies. The difference was found to be statistically significant (P C 0.002).

The average number of clinic visits among the cohort for their earlier pregnancies was four as shown in Table 5. When the average clinic visits were computed parity-wise, much variation was observed. The primi-parous women had an average clinic attendance as high as 6.3 while women of parity orders five and above had paid only 1.8 visits, on an average, to the clinic.

During the subsequent pregnancies, the average number of clinic visits was 3.4, the number varying from 3 to 4.2 for the different parity orders.

When the parity status of the women who had not attended the clinic at all was analysed (Table 6), it was found that during their earlier pregnancies, only 8.7 per cent of the primi-parae were found to be absent in comparison to 30 per cent and 38.9 per cent of the women belonging to parity orders four and five or above respectively. During the subsequent pregnancies, the proportion was seen to have decreased (5.7% of women of parity order two and 14.3% of women belonging to parity orders five and above).

Antenatal Tetanus Toxoid Immunisation-. The comparison between the antenatal tetanus immunisation during earlier and subsequent pregnancies of the cohort is given in Table 7. Only 6.5 per cent of the women could not be protected by tetanus toxoid administration during their subsequent pregnancies as opposed to 10.8 per cent likewise unprotected during their earlier pregnancies. Also, 69.4 per cent of the women were fully immunised in their subsequent pregnancies while only 53.9 per cent of the cohort had full immunisation during their earlier pregnancies. The differences observed were not significant.

TABLE 4
NUMBER OF ANTENATAL CLINIC VISITS DURING EARLIER AND
SUBSEQUENT PREGNANCIES OF THE COHORT

No. of Visits to Antenatal Clinic	Earlier	Pregnancy	Subsequent Pregnancy	
	Number	Percentage	Number	Percentage
5+	42	41.18	32	29.63
3-4	21	20.59	32	29.63
1-2	18	17.65	32	29.63
Nil	21	20.59	12	11.11
Total	102	100.00	108	100.00
X ² = 10.0787	d.f.= 3	P < 0.02	Significant	

TABLE 5
AVERAGE NUMBER OF ANTENATAL CLINIC VISITS IN RELATION TO
PARITY

Parity	Average Number of Antenatal Clinic Visits	
	Earlier Pregnancy	Subsequent Pregnancy
1	6.34	-
2	2.65	3.80
3	3.88	3.00
4	2.80	4.19
5+	1.83	3.00
Total	3.98	3.44

TABLE 6
PARITY STATUS OF WOMEN WHO HAD NOT VISITED THE ANTENATAL
CLINIC

Parity	Earlier Pregnancy		Subsequent Pregnancy	
	Number	Percentage of Total in that Group	Number	Percentage of Total in that Group
1	3	8.57	-	-
2	6	26.09	1	5.71
3	2	12.50	2	8.70
4	3	30.00	4	25.00
5+	7	38.89	4	14.29
All Parities	21	20.59	11	11.11

TABLE 7
TETANUS TOXOID IMMUNISATION DURING EARLIER AND SUBSEQUENT
PREGNANCIES OF THE COHORT

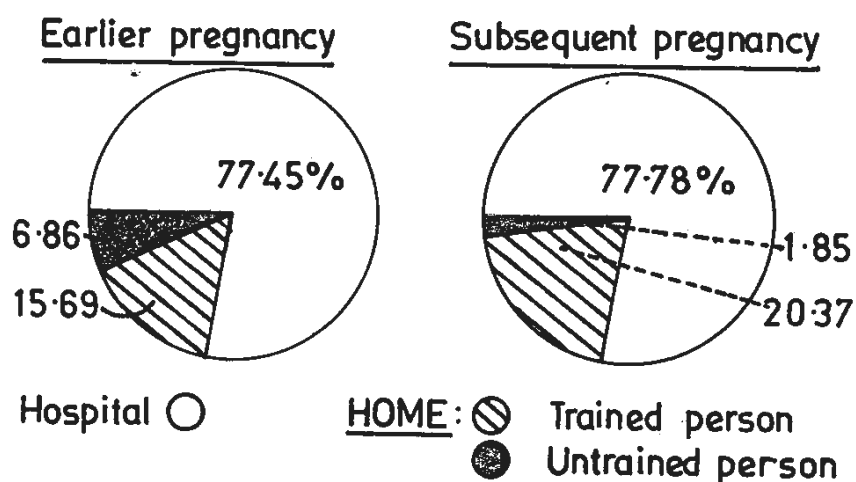
Immunisation Status	Earlier Pregnancy		Subsequent Pregnancy	
	Number	Percentage	Number	Percentage
Nil	11	10.78	7	6.48
Partial	36	35.29	26	24.07
Complete	55	53.92	75	69.44
Total	102	100.00	108	100.00

X²= 5.4729 d.f. = 2 P< 0.05 Not significant

Place of Delivery: Hospital deliveries outnumbered the home deliveries which were 78 per cent and 22 per cent respectively as shown in Table 8 and Fig. I, both for the earlier and for the subsequent pregnancies. Among the home-deliveries there was an increase in the proportion of deliveries conducted by trained traditional birth attendants or midwives for the subsequent pregnancies which was 91.7 per cent as compared to that in the earlier pregnancies of 69.6 per cent. A corresponding decline was observed among the deliveries conducted by untrained persons (8.3% of the subsequent and 30.4% of the earlier pregnancies delivering at home were attended by untrained persons).

TABLE 8
PLACE OF AND PERSON ATTENDING DELIVERY

Place and Person	Earlier Pregnancy		Subsequent Pregnancy	
	Number	Percentage	Number	Percentage
Hospital				
i. Trained personnel	79	77.45	84	77.78
Home				
i. Trained T.B.A. or Midwife	16	15.69	22	20.37
ii. Untrained person	7	6.86	2	1.85
Total	102	100.00	108	100.00



PLACE AND PERSON CONDUCTING DELIVERY - EARLIER AND SUBSEQUENT PREGNANCIES

FIGURE 1

Discussion

The cohort, in the present study, was found to consist a higher proportion of younger women than the group studied by Srinivasa et al.⁵ The ratio of women in the age group of 15 to 24 years to those aged 35 and above was 11.6:1 in the present study as compared to 1.5:1 in the previous one. Parity-wise also, there were more proportion of women of lesser parity orders, especially primi-parae, among the present cohort.

Fifty five per cent of the women in this study, were literate (a majority of them having been educated beyond the -primary school level) while, in the previous cohort, a minority of 35 per cent only were reported literate. Among the spouses also, the proportion of literate men was found to be higher in this study i.e. 86 per cent as compared to the previous figure of 70 per cent.

While, among the earlier cohort, 34.5 per cent were working, only 11 per cent of the present cohort were working women. This may be attributed to the better economic situation existing.

Amongst the spouses of the cohort, 2 per cent were pensioners, the rest being all gainfully occupied. The previous study had reported that 90 per cent of the spouses had some occupation or other while 3 per cent were pensioners and 7 per cent unemployed. The improvement in the occupational status may be due to the better level of literacy and itself accounts for the better economic status as 69.6 per cent of the families had a monthly income of more than Rs.200.

The women who sought antenatal care from their first trimester were 26.5 per cent during their earlier pregnancies while 39.8 per cent did so during their subsequent pregnancies. These data show a vast improvement over the situation prevailing earlier when only 4.1 per cent and 19.8 per cent of the cohort had registered during the first trimester, for their earlier and subsequent pregnancies respectively. Likewise, the incidence of late registration (i.e. after 24 weeks of pregnancy) showed a decline from 44.3 per cent and 21.8 per cent for the earlier and subsequent pregnancies in the previous study to 14.7 per cent for the earlier and 16.7 per cent for the subsequent pregnancies among the present cohort.

During their earlier pregnancies, the women paid four visits on an average to the antenatal clinic as compared to three by the cohort in the previous study. Primi-parae had the highest average clinic attendance of 6.3 visits. Those who did not attend the clinic at all were 20.6 per cent included, to a large extent, women of parity orders four and above. Only 8.6 per cent of the primi-parae stayed away from the clinic and during subsequent pregnancies, only 5.7 per cent of them still absented themselves.

The higher receptivity to maternal care services, among the present cohort in comparison to that among the earlier one, may be attributed to its composition and the importance attached to the advices imparted by the health staff visiting their houses and their observation of their neighbours benefitting from the services offered by the centre. The enhanced level of literacy might have also contributed to this improved receptivity. Having received the services once during the earlier pregnancies, they continued to make better utilisation of them during their subsequent pregnancies.

The lesser clinic attendance by women of higher parity orders may be ascribed to the -frequent visits paid by the staff of the centre to provide domiciliary care coupled with their feeling of security at having had previous safe deliveries. As many as 30 per cent of women of parity order four and 38.9 per cent of women of parity orders five and above did not attend the clinic even once during their earlier pregnancy. In the subsequent pregnancies, however, the proportion of absentees among these two groups taken together dropped down to 14.3 per cent, thus showing a progressive trend in the pattern of utilisation.

The coverage with tetanus toxoid was also observed to be better in the subsequent pregnancies when compared with that in the earlier ones. The proportion of cohort not covered fell to 6.5 per cent from 10.8 per cent and that fully covered rose to 69.4 per cent from 55 per cent. An associated factor in this enhancement of tetanus toxoid immunisation was that those covered fully during their earlier pregnancy required but one booster dose during their subsequent pregnancy for full immunisation. In the previous cohort, 17 per cent could not be protected with tetanus toxoid during their earlier pregnancies and 4 per cent during their subsequent pregnancies.

Study shows, almost equal proportions of women about 78 per cent delivered in the hospital during their earlier and subsequent pregnancies while, among the earlier cohort, 74.4 per cent sought hospital delivery for their earlier pregnancies and 62 per cent did so for their subsequent pregnancies. The reasons for increase in the desire for delivering in hospital were: (i) lack of facility at home because of over crowding; (ii) absence of a responsible family member to attend on her during delivery and afterwards; and (iii) medical advice.

The proximity of the Government Maternity Hospital at a distance of 1.5 kms may have also influenced their decision.

The proportion of the total deliveries conducted by untrained persons was 13.8 per cent in case of earlier pregnancies and 11.7 per cent for subsequent pregnancies in the previous study. There was a dramatic declining trend with only 6.9 per cent and 1.9 per cent of the present cohort seeking untrained persons for the conduct of their deliveries for earlier and subsequent pregnancies respectively, the rest all having trained personnel, either at hospital or at home, in attendance at the time of their deliveries. This shows the impact of the health education and advice given by the staff of the health centre.

Thus, we observe that the criteria suggested by Srinivasa et al. can be employed in the evaluation of the quality of maternal care services rendered. The various parameters utilised suggested an overall improvement among the present cohort in their receptivity to the services provided as compared to the cohort studied some years back. Though the various characteristics of the cohort do have some influence, the role played by the staff of the health centre is considerable in ensuring adequate utilisation of the services by the women.

Acknowledgement

The authors are grateful to Dr. M.N. Ghosh, Director, Jawaharlal Institute of Postgraduate Medical Education s Research, Pondicherry for his encouragement. Thanks are also due to the staff of the Urban Health Centre and the cohort for their cooperation.

Lkkjk'k

शहरी स्वास्थ्य केन्द्र, पाण्डीचेरी द्वारा प्रदान की जाने वाली मातृ-स्वास्थ्य देखरेख सेवाओं की उपयोगिता के प्रति हो रहे परिवर्तन का अनुमान लगाने हेतु 102 महिलाओं के एक ऐसे समूह का अध्ययन किया गया, जो एक निश्चित अवधि में एक से अधिक बार गर्भवती हुई थी। अध्ययन के परिणामों की तुलना इससे पूर्व किये गये इसी प्रकार के अध्ययन के परिणामों के साथ की गई है।

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REACTION OF PATIENTS TO STD INFECTION

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ABSTRACT

The study was conducted on 150 new STD cases and an equal number of matched controls. It was found that STD patients travelled a larger distance for treatment. Most STD patients consulted qualified practitioners for treatment and sought treatment quite early.

Sexually transmitted diseases are a public health problem in most countries of the world. The commonest approach towards solving this problem is by establishing curative services in the form of STD clinics. India, too has these clinics under the National STD Control Programme. It is, therefore, of very vital importance to know the reaction of STD patients to their infection particularly with regard to whom they contacted for treatment, how long they took to do so and where they went for treatment. Knowledge about these reactions is essential for planning the future strategy for the control of STD. Keeping this in view the study was conducted at JIPMER, Pondicherry.

Material and Methods

The study was carried out from November 1981 to May 1982 on a group of 150 consecutive new STD patients and the results compared with an age and sex matched of 150 new patients drawn from the Dermatology OPD. Any patient who had a past or present history of STD infection or reacted positively to the VDRL test was excluded from the control group.

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The data was collected by interviewing the patients in privacy with the help of a pretested proforma after assuring them of the confidentiality of the information so obtained.

The distance travelled by a patient was calculated using a road map.

Findings

Place of Origin

It was observed that only a small minority of patients in the STD group 21.33 per cent had come from the local town as against almost half the patient in the control group 38.67 per cent. This difference was found to be statistically significant. There were a large number of patients from both STD and control groups who had come from South Arcot District (49.33% and 44% respectively), and a small number from other districts. These differences were however not statistically significant as shown in Table 1.

TABLE 1
PLACE OF ORIGIN OF PATIENTS AND CONTROLS

Place of origin	Cases		Controls	
	No. of Patients	Percentage	No. of Patients	Percentage
Pondicherry	22	14.67	12	8.00
Pondicherry Town	32*	21.33	58*	38.67
South Arcot	74	49.33	66	44.00
Madurai	0	-	1	0.67
Tanjore	4	2.67	0	-
Tiruchy	1	0.67	0	-
Salem	5	3.33	4	2.67
Dharmapuri	2	1.33	0	-
North Arcot	9	6.00	8	5.33
Ramanathapuram	1	0.67	1	0.67
Total	150	100.00	150	100.00

•Difference statistically significant - P less than .01.

Distance Travelled

It was found that the number of STD patients who had travelled less than 5 km was less than half the number of controls who had travelled the same distance (20.67% and 42% respectively). In all other class intervals, however, there were more STD patients than controls. These differences are shown in Table 2 which were highly significant.

Persons Consulted for Treatment

It was also found that among STD patients almost half of them (48%) and first consulted a private practitioner for treatment while a slightly smaller number (40.67%) had come directly to JIPMER. A small number had contacted quacks (6%) and government doctors, government hospitals and PHCs (5.33%). In the control group, however, 55 per cent had come directly to JIPMER while 37 per cent went to private practitioners, 8 per cent to government doctors and none to quacks. This difference was statistically significant.

TABLE 2
DISTANCE TRAVELLED BY PATIENTS AND CONTROLS

Distance travelled (Km.)	Cases		Controls	
	No. of Patients	Percentage	No. of Patients	Percentage
Less than 5	31	20.67	63	42.00
5 - 25	32	21.33	18	12.00
25 - 50	36	24.00	36	24.00
50 - 100	18	12.00	13	8.67
100 - 200	27	18.00	16	10.67
200 - 300	5	3.33	1	0.67
More than 300	1	0.67	3	2.00
Total	150	100.00	150	100.00

Difference significant P less than .05.

Reasons for Patients Coming to JIPMER

It was found that 48 per cent of STD patients had come to JIPMER after consulting somewhere else (Table 3). Most of these patients came because there was no improvement (36%) while some were referred (12%). in the controls, however, the corresponding figure was only 30.67 per cent and 9.33 per cent.

More STD patients than controls came to JIPMER because they were told by friends that treatment given was good (23.33% and 16% respectively) while fewer of them came because it was the closest hospital (14.67% and 26.67% respectively). Only 9.33 per cent of the STD patients had come to JIPMER for anonymity.

As many as 17.33 per cent of the controls had come here for 'other reasons' (accompanying friends or relatives for treatment) while only 4.67 per cent of STD had come for the same reason.

TABLE 3
REASONS FOR STD PATIENTS COMING TO JIPMER

Reasons	Cases		Controls	
	No. of Patients	percentage	No. of patients	percentage
No improvement	54	36.00	46	30.67
Advised by friends	35	23.33	24	16.00
Closest hospital	22	14.67	40	26.67
Referred	18	12.00	14	9.33
Anonymity	14	9.33	0	–
Others	7	4.67	26	17.33
Total	150	100.00	150	100

Difference significant p less than .05

Time Interval Between Onset and Treatment

It was found that 44 per cent of STD patients had sought treatment within one week of developing symptoms against 17 per cent in the control group. Similarly, only 34 per cent of STD cases had reported after one month against 70 per cent of the controls. These differences were highly significant and are given in Table 4.

Discussion

The data revealed that STD patients come from a wider area and travel over longer distance than controls for seeking treatment. This probably reflects the fact that we do not have an adequate number of STD clinics in this area and patients have to travel long distance to seek treatment.

Almost three fifths of the STD patients had come to JIPMER either because treatment elsewhere was not adequate or because they were told by friends that good treatment was available here. This reflects on the existing health delivery system and it may be surmised that both the private practitioners and the government doctors are either not receptive to these patients or are not competent enough to properly diagnose and treat these diseases. A very small number of patients had come to JIPMER for the sake of anonymity and therefore it is re-emphasised that the longer distances travelled by these patients is either due to the non-availability or the inadequacy of the existing health services.

TABLE 4
TIME INTERVAL BETWEEN ONSET AND TREATMENT

Duration	Cases		Controls	
	No. of Patients	Percentage	No. of Patients	Percentage
0-7 days	66	44.00	26	17.33
8-14 days	14	9.33	6	4.00
15-30 days	19	12.67	12	8.00
1-6 months	51	34.00	86	57.33
6-12 months	0	-	14	9.33
More than 12 months	0	—	6	4.00
Total	150	100.00	150	100.00

Difference significant p less than .05

Findings similar to the above have been reported by Saha et al. and Bhargava et al. but they have not compared their findings with controls. However, an encouraging point that was discovered in the study was that 94 per cent of the patients had contacted qualified medical practitioners. Other authors have however reported a larger number of patients contacting quacks (Saha et al.⁴ and Kapoor et al.).

In this study, STD patients were found to seek treatment quite early. Other authors have also reported similar findings (Ranganathan et al. and Kapoor et al.). This is probably because of the distressing symptoms that these diseases cause.

It is, therefore, concluded that even though STD patients seek treatment early they often have to travel long distances and consult at a number of places for getting relief even though they consult qualified practitioners. The need therefore exists for setting up of more STD clinics and more adequate training of our practitioners.

Acknowledgement

The authors wish to thank the Director, Jawaharlal Institute of postgraduate Medical Education and Research, Pondicherry for according us permission to conduct this study.

We are also grateful to Dr. Sardari Lai, Head of the Department of Dermatology and STD for the help during the study.

सारांश

यौन संक्रामित रोग (एस टी डी) से ग्रस्त 150 नये रोगियों पर तथा इतनी ही संख्या में समेल नियन्त्रित रोगियों पर एक अध्ययन किया गया है कि एस टी डी रोगियों ने इलाज के लिए एक बहुत लम्बा रास्ता तय किया गया है। अधिकांश एस टी डी रोगियों द्वारा इलाज कराने हेतु अहर्ताग्रस्त चिकित्सकों से सलाह ली गई थी तथा उनका इलाज शीघ्र ही हो गया था।

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USE OF A SINGLE SILASTIC IMPLANT RELEASING NORETHINDRONE
ACETATE FOR THE CONTROL OF CONCEPTION: A REVIEW

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ABSTRACT

A single stastic implant containing 40 mg norethindrone acetate (NETA) is one of the long-acting contraceptive devices for woman. The in vivo release rate of NETA from this device is within the range of T28 to 188 jig/day in women, rats and rabbits. However, the serum norethindrone (NET) concentration has been found to be around 1 ng/ml in women, rabbits and rhesus monkeys after insertion of an implant for six to eight months. The contraceptive efficacy of this device is high. The pregnancy rate is only 2.2 to 3.9 per 100 women at the end of three months after insertion of the implant. There is incidence of disturbance in the normal hormonal profile in women, indicating the suppression of ovulation in some of the cases. The cycle abnormalities decrease with the prolongation of treatment. No metabolic disorders have been observed in women in various clinical trials with this device. The single silastic implant releasing NETA appears to be well acceptable to women for the control of conception.

A silastic implant releasing contraceptive steroid appears to be one of the important long-acting methods for the control of conception. Owing to the constant in vivo release of steroid from a polydimethyl siloxane implant and subsequent maintenance of an uniform steroid level in plasma, the subcutaneous implant has an advantage over the long-acting injectables because the latter cannot be withdrawn from circulation, in case there is an emergency, in addition to the bleeding problem due to the uneven steroid level in plasma.

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The implant method of administration of hormonal contraception has also overcome the disadvantage of daily intake of oral pill although this subcutaneous long-acting method per se has its own demerit. Multiple devices that is three to six or even 12 implants of norethindrone and three to six implants releasing norgestrel have been clinically evaluated for their contraceptive efficacy. While the use of multiple implants was necessary to release sufficient amount of steroid in the body to produce the desired contraceptive effect, it appears doubtful if the use of multiple implants actually produced the multifold increase in the amount of steroid released in the body and multifold levels of steroid in plasma. This becomes obvious from some of the studies¹- where even four implants of megestrol acetate, norethindrone or norgestrel used to increase the plasma level of steroids, did not evoke 100 per cent contraceptive effect. On the other hand, the introduction of a single silastic implant releasing norethindrone acetate to prevent pregnancy in woman actually pushed the long-acting implant device a step ahead in the race of being a widely acceptable contraceptive method.

The study presents a complete review on the single silastic implant, also known as implant-D, releasing norethindrone acetate for contraception.

Methodology

Preparation of Implant

The polydimethyl siloxane (silastic) tubing (No.602-301; Dow Corning Corp., Midland, Michigan, USA) having I.D. of 0.078 and O.D. of 0.125 inches, was cut into one foot long pieces and washed with soft soap water followed by running distilled water. Pieces of this tubing of 22 mm in length were washed in azotropic mixture of isopropyl alcohol and water, dried in a desiccator and sealed at one end with fresh medical grade silastic adhesive (type A). Each piece was filled with 40 mg crystalline or amorphous NETA. The open end was sealed with silastic adhesive. Subsequently, each implant was rinsed by dipping once or twice in 50 per cent methanol to remove any steroid adhered on the surface of it during the filling process and was dried in a vacuum desiccator. Each implant was packed in polythene bag and was sterilised by anprolene gas (ethylene oxide) in an Anprolene steriliser AN-74. The implant thus prepared is also known as an inplant.

In vitro Release Rate of NETA

The in vitro release rate was determined by incubating the implant in 20 ml of 0.9 per cent sodium chloride solution at 37°C in a constantly shaking water bath (Dubnoff metabolic shaker) at 60 to 70 strokes/min. The medium was changed every 24 h. Steroid, released in the medium was extracted with ethyl acetate three times using an equal volume of solvent each time. The pooled extract was dried under nitrogen. The residue was redissolved in 10 ml of methanol. The quantitation of the steroid was done spectrophotometrically at 240 nm against methanol blank.

Insertion of Implant

In women: The implant was subcutaneously inserted with the help of a 11 gauge trocar cannula on the lateral side of the thigh using 1 per cent Xylocaine as a local anaesthetic. The proper sterile condition was maintained during the insertion of the implant in all the cases.

In rats : The rat was anaesthetised with ether and thereafter, the implant was subcutaneously inserted in the nape region with the aid of the 11 gauge trocar cannula.

In rabbits: The implant was subcutaneously inserted in the thigh of hind legs or/and in the deltoid region of forelegs with trocar cannula using 2 per cent Xylocaine as a local anaesthetic.

In monkeys: The implant was subcutaneously inserted in the thigh of hind legs or/and in the deltoid region of fore-arms with trocar cannula under general anaesthesia with Nembutal (Parke Davis).

In vivo Release of NETA

Implants removed at the termination of the experiment were cleared off from any adhering foreign bodies and were cut open into vials containing 10 ml methanol. These were then left for about 6 h and the supernatant containing steroid was decanted. The pieces of silastic were washed once again with 10 ml of methanol and the methanol extract was pooled. Steroid extracted in methanol was estimated, after appropriate dilution, spectrophotometrically at 240 nm.

nm using Beckman (model 25) spectrophotometer. The release rate of NETA (µg/day) was determined on dividing the amount of total release by number of days the implant was in situ.

Blood Sample Collection

Blood samples were collected from women or animals weekly or fortnightly after insertion of implants. Serum was separated and stored in 1 ml serum vials at -70°C or at -20°C until they were analysed for NET¹⁴.

Estimation of NET

Serum NET concentration in women, rabbits and monkeys were estimated by radioimmunoassay technique using specific antibody for NET.

Statistical Analysis of Data

In most of studies, simple statistics was used to calculate the mean and standard deviation. In a few cases, two way analysis of variance and Newman Keul's multiple range analysis methods and life-table method of Tietze were also used.

Results

In vitro Release of NETA

The release of rate of NETA from the implant between 0-7, 0-24, 0-120 and 0-210 days were reported to be 90.6, 81.3, 76.7 and 74.9 µg/day, respectively.

In vivo Release of NETA

In women: In a clinical trial with 85 women for 282 woman-months, the in vivo release rate of NETA from an implant was found to be 128 µg/day. However, it was reported to be 202.4 µg/day in another trial with 324 women out of which only 98 women reported for removal of implants upto 7 month, in the cases where implants were removed at intervals greater than 210 days, the apparent release rate were calculated by dividing the amount of steroid released from the implant by 210 days only rather than dividing by the

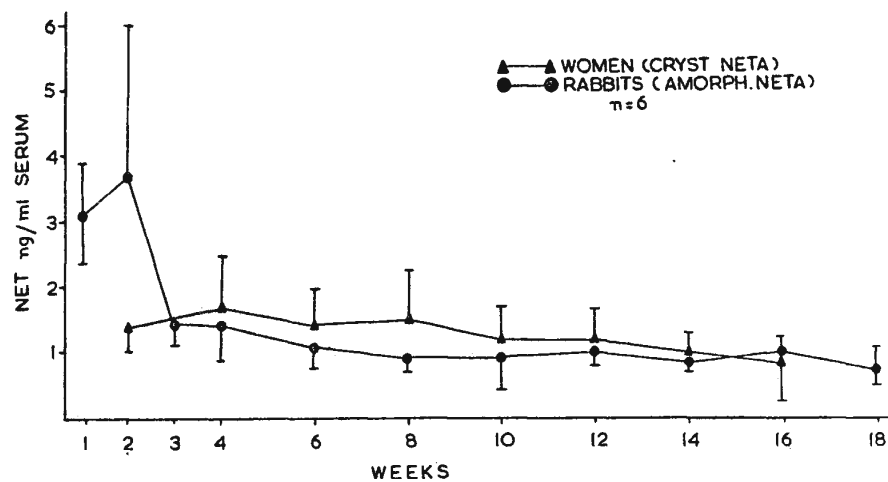
actual number of days. The release rate thus calculated were reasonably constant from 90 to 210 days and was in an average of 188.9 jig/day.

In animals: In an experiment on rats with these implants over a period of two to six months, the average release rate of NETA was 'observed to be 141 pg/day, whereas in another study, it was reported to be 339.3, 160.3, 151.2 and 135.0 jig/day between 0-7, 0-24, 0-123, and 0-210 days of the treatment period, respectively. However, after insertion of 1, 2 and 4 implants in three groups of rabbits, the in vivo release rate of NETA was estimated to be 131.8, 122.6 and 128.3 jag/day/implant, respectively over 24 week treatment period.

Plasma NET Concentration

In Women: The pattern of serum NET levels in six women after insertion of an implant was found to be 0.78 to 0.85 ng/ml between 100 to 200 days after insertion. The mean value of NET at 100 days was of the order of 0.78 ng/ml. The circulating NET levels in another group of 26 women slowly declined with the prolonged duration of use. There were marked individual variation of NET levels throughout the study period of 25 weeks. It was also observed that serum NET levels in 25 lactating women estimated over a period of seven months indicated that levels of NET were high of the order of 5 ng/ml serum in first two weeks. In next two weeks, levels, fell to an average value of 1.5 ng/ml serum, which were maintained in the second month. Prom the second month, levels of NET declined to an average value of 1.0 ng/ml and remained constant upto the 6th month followed by subsequent decline to 0.5 ng/ml in the 7th month. In another study with six women, the mean NET level was 1 ng/ml in the second treatment cycle of two subjects and in the first and third treatment cycles of one subject, it was further reported that after insertion of silastic implants in six women the mean serum NET level was within the range of 1.5 to 1.4 ng/ml upto the 8th week. Thereafter, it was almost constant around 1.2 ng/ml upto the 12th week. This again declined to a level of 1,0 ng/ml at the 14th week and even 0,9 ng/ml at the 16th week of the treatment period (Fig, 1) .

In rabbits: Concentrations of NET in. serum were estimated in three groups of female albino rabbits (5



SERUM NET LEVELS (MEAN+SD) ATTAINED IN WOMEN AND RABBITS AFTER SUBCUTANEOUS INSERTION OF A SINGLE SILASTIC IMPLANT CONTAINING 40 mg AMORPHOUS OR CRYSTALLINE NETA (Ref. 13)

FIGURE 1

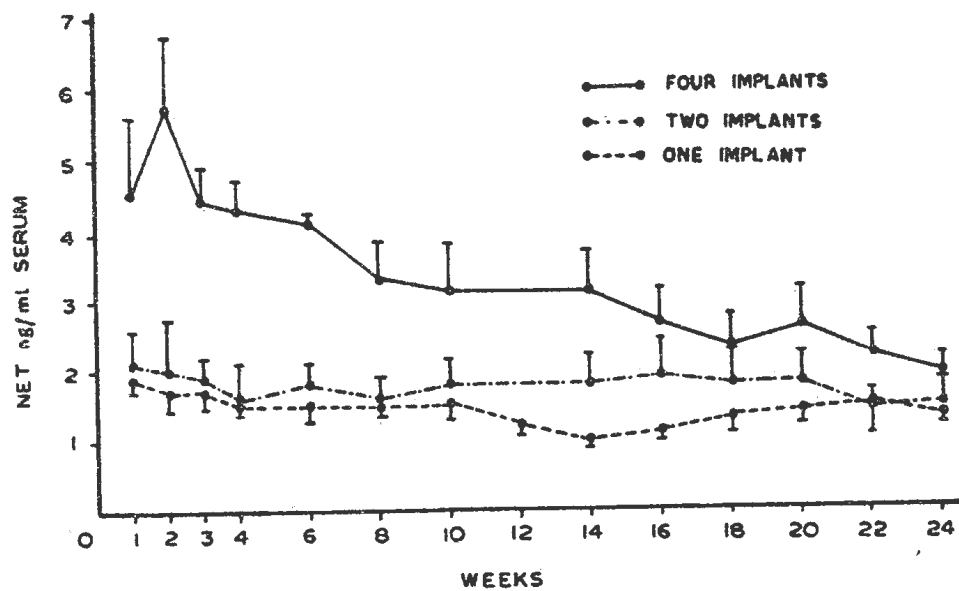
animals/group) after subcutaneous insertion of 1, 2 and 4 implants over a period of 24 weeks (Fig. 2). The mean of serum NET level was found to be 2.0 to 1.5 ng/ml in group I (one implant), 2.1 to 1.5 ng/ml in group II (two implants), and 4.6 to 2.0 ng/ml in group III (four implants). The marked individual variation in serum NET levels was observed in animals of group II and III. The mean of ratios of mean NET levels for entire 24 weeks was 1.2 in group II and 2.4 in group III when compared with that of group I taken as 1. Thus interestingly, the serum NET level did not show the expected twofold and fourfold increase with two and four implants, respectively.

After the insertion of a single implant containing amorphous NETA in six rabbits, the mean serum NET level was found to be 3.1 ng/ml in the 1st week and 3.8 ng/ml in the second week. The NET level then fluctuated between 1.4 to 1.0 ng/ml upto the 18th week of the treatment period¹¹ (Fig. 1).

On keeping an implant in the vagina of five rabbits to ascertain the diffusion of NETA through the vaginal mucosa, it was observed that the, mean serum NET level declined from 5.6 ng/ml on day 7 to 3 to 1.8 ng/ml on day 19 and thereafter fluctuated between 0.5 to 0.3 ng/ml upto the 25th week of the treatment period. Deposition of organoinorganic salts over implants was observed and seemed to be causative factor for sharp decline in serum NET levels in this study.

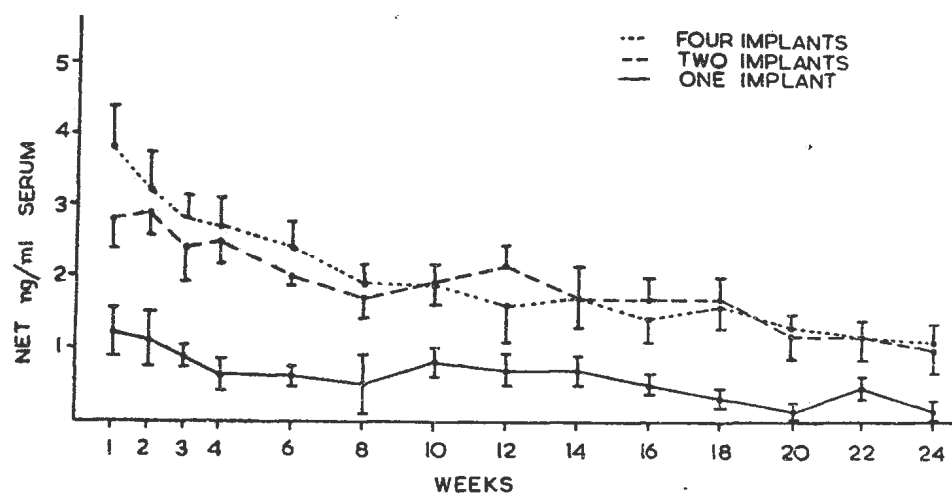
In monkeys: The serum NET levels were studied in three groups of female rhesus monkeys (6 animals/group) after subcutaneous insertion of 1, 2 and 4 implants over a period of 24 weeks (Fig. 3). The mean of serum NET levels was found to be 1.2 to 0.1 ng/ml (range) in group I (one implant), 2.9 to 1.0 ng/ml in group II (two implants) and 3.8 to 1.1 ng/ml in group III (four implants) over the treatment period. The individual variation in serum NET levels was also observed in all groups of monkeys.

The results of these studies indicated that the serum NET level could not be predicted from the number of the implant inserted. It could also be stated conclusively that with a single silastic implant, the serum NET value in woman was similar to that found in rabbits, while in rhesus monkeys the level of NET was comparatively low.



SERUM NET LEVELS (MEAN $\pm$ SE) IN RABBITS AFTER INSERTION OF SINGLE IMPLANT (GROUP I), TWO IMPLANTS (GROUP II) AND FOUR IMPLANTS (GROUP III) (Ref. 13)

FIGURE 2



SERUM NET LEVELS (MEAN±SE) IN MONKEYS AFTER INSERTION OF SINGLE IMPLANT (GROUP I), TWO IMPLANTS (GROUP II) AND FOUR IMPLANTS (GROUP III) (Ref. 13)

FIGURE 3

Effect on Endogenous Hormones

After insertion of implants in four women for eight months, some cycles of first few months showed normal ovulatory pattern of hormone levels, while others showed some disturbances in the hormonal pattern. As compared with the control cycle, serum progesterone levels tended to be low during the luteal phase in most of the treatment cycles. Mid cycle FSH and LH peaks in the first three treatment cycles of six women were either abolished or distinctly present. Follicular and luteal phase LH levels were invariably suppressed throughout the cycle lying below a level of 100 ng/ml, while FSH levels remained usually high with several spikes in five subjects ranging from 100 to 400 ng/ml. Progesterone was suppressed in all the initial treatment cycles. Levels were below 2 ng/ml serum. This included 2nd treatment cycles of five subjects and 1st and 3rd treatment cycle of one subject. Estradiol was quite erratic with unusually high and fluctuating levels showing several peaks in all subjects. However, in the first and 3rd treatment cycles of one subject, the estradiol level remained suppressed like that of progesterone. In the 6th treatment cycle, FSH and LH showed a distinct mid-cycle rise, but LH peaks and, in one case, FSH peak were much lower and broader as compared with control cycles. It was interesting that mid cycle LH peaks were much lower than FSH peaks. Like initial treatment cycle, the FSH level remained high throughout the cycle with several sharp peaks. The range was 100 to 600 ng/ml.

Effect on Other Systems

The effect of constant release of steroid from the implant inserted in 79 women on tissues and organs like blood, liver, kidney and adrenal gland etc. was studied. Each subject in pretreatment state served as her own control. Throughout the period of observation, no abnormality was detected, in the general, physical, systemic and pelvic examinations. Blood pressure remained within normal limits. There was no significant changes in the body weight. Papanicolaou smears taken at the time of implant removal were all negative. The value of hemoglobin, packed cell volume, ESR, total leucocytes and differential count, platelets, reticulocytes were well within the normal range. Values of serum glutamate-oxaloacetate transaminase, serum glutamate

pyruvate transaminase and serum albumin were in the normal range. There was no change noted in the values of total serum protein, bilirubin and alkaline phosphatase. The routine analysis of urine revealed that there was no change in the kidney function after implant insertion. Values of fasting blood sugar, triglycerides, plasma Cortisol and protein bound iodine were in no way affected by the implant. The cholesterol value was declined in the treated, group, but it was still within the normal range.

The long-term effect of the implant on lipid metabolism was also investigated in female rhesus monkeys. Apart from the transient increase in serum triglycerides level in the initial two to three months of implant insertion, the serum cholesterol, phospholipids and free fatty acids remained normal over 19 months of treatment.

Effect on Breast Milk

A study was carried out to evaluate the impact of implant on milk in 35 women at post-partum period. Of these 23 women received implants on the 6th day after delivery (group I) and 12 women received implants at six weeks after delivery (group n). Fifteen women using conventional contraceptives served as the control group. A transient fall in milk protein at two weeks of implant insertion was observed in group I. A decrease in milk phosphorus content was also found between two to four months after implant insertion in group I. No significant change was detected subjectively about the quantity of milk from the previous pregnancy in-all subjects. No qualitative changes in chemical constituents of milk were found in group II as compared with the control group.

Tissue Reaction Around Implant

The tissue reaction at the site of implant insertion was evaluated in 50 women. Clinically, induration over the implant was detected in only one of than. The histopathology revealed that there was a connective tissue response to the silastic implant. The connective tissue showed progressive condensation and maturation of collagen was associated with chronic inflammatory cell reaction, mainly mononuclear cells and foreign body giant cells. New capillary formation was also seen. However, no anaplastic changes of the fibroblasts were observed.

Bleeding Problem and Other Side Effects

In a study of 86 women for 282 cycles it was reported that 20 per cent of the women experienced menstrual irregularities with the implant-D as compared with 9 per cent of them having menstrual abnormalities even before insertion of implant. However, in another study, ten out of 26 women had regular bleeding throughout the study period except for an occasional spotting. The 16 women had irregularity in bleeding for at least six months after insertion of implants. It was interesting to note that these women who had initial high release of NET roughly more than 1.5 ng/ml in the first three weeks after insertion of implants, invariably had irregular bleeding. In a study⁸ with 255 women for a period of 1196 woman-months, it was observed that abnormalities in the menstrual pattern showed a decline with time. Analysis further revealed complaints like pain in the abdomen or back, irregular bleeding and dizziness gradually diminishing with the prolongation of treatment period. There were no thromboembolic phenomena and breast disorder reported in the trial. In another study^{1^} with ,876 women for 3975 woman-months, it was found that percentage of abnormal cycles manifested with menorrhagia, metrorrhagia, amenorrhoea, oligomenorrhoea and polymenorrhoea declined in prolonged treatment with implants. There was further report that duration of menstruation appeared to be normal after insertion of implants. However, there was occasional spotting in some of the subjects studied.

Efficacy and Acceptability

In a study with 876 women for 3,975 woman-months of the implant insertion, it was shown that the pregnancy rate were 2.3 and 3.9 per 100 women at the end of seven and eight months, respectively. The rate of removal of the implant for medical ground was 5.7 per cent for personal reason was 1.2 per cent and for planning pregnancy was 0.6 per cent, with the resultant total termination rate of 13.6 per 100 users at the end of eight months. The continuation rate for the same time was 96.4 per 100 women. In another clinical trial with 255 women for 1,176 woman-months, it was reported that total cumulative continuation rate was 87.1 per 100 women at the end of six months, whereas, the rate of discontinuation due to pregnancy was 2.2 per 100 women at six months and discontinuation at the clinic due to personal reason was

only 0.6 at the end of six months. Bleeding was reported as the main cause of removal of the implant. Women accepted the implant method were parous (P^{2+2}) and of 25 years old (average) . Most of them belonged to the middle class educational group.

General Discussion

The single silastic implant releasing norethindrone acetate is one of the acceptable subcutaneous long-acting contraceptive devices. The in vivo release rate of NETA from the implant was similar in rats and rabbits, while there was a slight difference in the reported values of the release rate of NETA in women. This numerical discrepancy, probably evolved out of the statistical analysis of unequal variables such as duration of exposure and number of women included in various studies. However, it was observed that the daily release of NETA from an implant was within the range of 128 to 188 jig in three species vis. rats, rabbits and women.

The serum NET concentration attained after insertion of an implant was around 1 ng/ml in animals and women. The study in rabbits showed that the single implant may be effective even for an year. The combination oral pill containing NETA produced serum NET concentration of 1 to 3.5 ng/ml in women during the first treatment cycle. The NET level from a single implant was very static over a long period. Similar result was also observed with the vaginal device having two mini implants, each containing 20 mg NETA. Thus, the use of single silastic implant seemed to be advantageous over the use of multiple implants releasing other steroids to achieve the same objective. There was disturbance in menstrual cycles in the initial stage of the treatment with the implant. This might be due to the initial high release of NETA. It was found that the side effects including spotting and bleeding decreased with the subsequent stabilisation of release rate of NETA¹⁰. There was no detectable effect of circulating NET on the general metabolism and function of vital organs like liver and kidney, although there was a change in the normal endogenous hormonal profile indicating that the hypothalamo-hypophysial-gonadal axis was affected.

This single, implant device appeared to be well acceptable to woman because of its small size, prolonged effectiveness and less side effect. The insertion and/or removal of

this implant involved very minor injury which did not affect the physical and mental health of woman.

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40 एम.सी. नार—एथिनड्रान एसीटेट (एन ई टी ए) से युक्त एक साइलास्टिक निरोपण महिलाओं के लिए गर्भ निरोधक के तरीकों में से एक ऐसा तरीका है जो दीर्घकाल तक प्रभावी रहता है। इस तरीके से महिलाओं, चूहों तथा खरगोशों के इन-विवों से एन ई टी ए का विर्सजन दर प्रतिदिन 128 से 188 यू जी की श्रंखला में होता है। किन्तु यह देखा गया है कि 6 से 8 माह तक एक निरोपण सन्निविष्ट कराये जाने के उपरान्त महिलाओं, खरगोशों तथा रेहसस बानरों में सीरम नार—एथिनड्रान (एन ई टी ए) का जमाव लगभग 1 एन जी एम एल था। इस विधि की गर्भनिरोधक क्षमता बहुत उंचे स्तर की है। निरोपण सन्निविष्ट होने के पश्चात तीन माह की अवधि के अन्त में गर्भधारण की दर 100 महिलाओं पर 2.2 से 3.9 के बीच रह जाती है। महिलाओं की सामान्य हारमोनल स्थिति में गड़बड़ होने की घटना सामने आई है, जिससे संकेत मिलता है कि कुछ केसों में डिम्बक्षरण की क्रिया निश्क्रिय हुई। लम्बी अवधि तक उपसा चलते रहने से मासिक धर्म संबंधी असमानताओं में कमी आती है। इस विधि संबंधी विभिन्न औषधालीय प्रयोग करते समय महिलाओं में किसी प्रकार का चयापचयी विकार नहीं देखा गया। एन ई टी ए विर्सजन करने वाला एकल साइलास्टिक निरोपण सम्भवतः महिलाओं में गर्भ-धारण को रोकने के लिए सबसे अधिक स्वीकार्य तरीका है।

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