ıment 1.

Date 11.12.81

ETHICAL REVIEW COMMITTEE, ICDDR,B.

60

ipal Investigator Dr. P. Speelman

Trainee Investigator (if any) Dr. William Brinton

cation No. 81-051(P)

Supporting Agency (if Non-ICDDR,B)

of Study Retrospective Study of

Project status:

ellosis at ICDDR,B Hospital

(X) New Study

(Limited Study)

( ) Continuation with change

( ) No change (do not fill out rest of form)

e the appropriate answer to each of the following (If Not Applicable write NA).

ource of Population:

a) Ill subjects (Yes) No

b) Non-ill subjects Yes (No)

c) Minors or persons under guardianship (Yes) No

oes the study involve:

a) Physical risks to the subjects Yes (No)

b) Social Risks Yes (No)

c) Psychological risks to subjects Yes (No)

d) Discomfort to subjects Yes (No)

e) Invasion of privacy Yes (No)

f) Disclosure of information damaging to subject or others Yes (No)

oes the study involve:

a) Use of records, (hospital, medical, death, birth or other) (Yes) No

b) Use of fetal tissue or abortus Yes (No)

c) Use of organs or body fluids Yes No

e subjects clearly informed about:

a) Nature and purposes of study Yes No WA

b) Procedures to be followed including alternatives used Yes No

c) Physical risks Yes No

d) Sensitive questions Yes No

e) Benefits to be derived Yes No

f) Right to refuse to participate or to withdraw from study Yes No

g) Confidential handling of data Yes No

h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

5. Will signed consent form be required:
   (a) From subjects Yes No
   (b) From parent or guardian (if subjects are minors) Yes No
6. Will precautions be taken to protect anonymity of subjects Yes No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ___ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidentiality
   ✓ Questionnaire or interview schedule

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

ee to obtain approval of the Ethical Review Committee for any changes
ing the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

81-051(P)
Rec'd: 12-12-81

SECTION I - RESEARCH PROTOCOL

1. Title: A Retrospective Study of Shigellosis at ICDDR,B Hospital

2. Investigators: Dr. W. Brinton
Dr. Iqbal Kabir
Dr. P. Speelman

3. Starting Date: 1 November 1981

4. Completion Date: 1 March 1982

5. Total Direct Cost: US $2,675

6. Scientific Program Head:

This protocol has been approved by the Pathogenesis - Therapy Working Group.

Signature of Scientific Program Head: T. Butler

Date: 4 Dec 1981

7. Abstract Summary:

In this limited study, we will review the charts of patient with shigella infection, admitted to ICDDR,B hospital in 1980. The available data will be used to determine if a relationship exists between the presenting clinical or laboratory features and subsequent complicated illness.

Data will be recorded on data sheets and entered on computer discs for analysis. The results of this limited study will serve as a guide for a prospective study on the complications of shigellosis.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

The main objective of this study is to identify any correlation between the presenting features of shigella cases and complications in the clinical course.

2. Background:

Shigella is a major pathogen in Bangladesh, causing 5.8% of infections at the field hospital of ICDDR,B in Matlab from 1977 to 1980 (Hossain et al, Abs, 1980). The morbidity and mortality of shigellosis is high- death rates for hospitalized cases in Bangladesh are 5 to 8% (M.U. Khan, manuscript).

In addition to dehydration from intestinal fluid loss, the serious enteric complications of shigellosis include: rectal prolapse, massive colonic hemorrhage, toxic megacolon, and colonic perforation with peritonitis, localized abscess or liver abscess. Also, colonic strictures may form following severe bacillary dysentery. However, most of these problems are quite rare (Sleisenger and Fordtran, 1978. pp.1630,1680).

Shigellosis is frequently associated with extra intestinal disease. Complications may arise in a number of organ systems, adding to the already high morbidity and mortality of shigella enterocolitis. Respiratory symptoms of cough or coryza are common. In one series of

shigella patients (Barrett-Connor and Connor, 1970), pulmonary infiltrates were noted on 10% of admission chest X-rays, though only a minority of patients received radiographs. Pneumonia appears to be a common complication of diarrhoeal disease, shigella included, at ICDDR,B hospital (Dr. Alam, pers. comm.)

Hematologic derangements are frequent in shigellosis. Leukemoid reactions (>50,000 WBC's) were present in 16% of cases with Shiga diarrhoea (Rahaman et al, 1975) and 25% of cases due to any species of shigella (Koster et al, 1978). Twelve percent of cases in the latter study had a syndrome of leukemoid reaction, hemolytic anemia, and thrombocytopenia, all tending to occur late in the disease course, when other clinical parameters were improving.

Renal compromise in shigellosis ranges from mild pre-renal azotemia to frank hemolytic-uremic syndrome(HUS), which appears to be uniquely associated with marked leukocytosis. The mechanism is unknown, but HUS may be endotoxin induced (Koster et al, 1978). In this study, the incidence of HUS was nearly 5% in childhood cases of shigellosis admitted to ICDDR,B hospital from 1975 to 1976. Anecdotal reports indicate that this syndrome is seen less frequently at present.

Seizures are commonly present in shigella cases. Barrett-Connor and Connor (1970) identified seizures in 13% of shigella cases (both S. flexneri and S. sonnei). Most often, convulsions are associated with fever. However, in 7% of cases from Knowlesson and Forbes (1958), T_{max} was less than 102°F. There was no fever in a small minority of

seizure cases in Barrett-Connor and Connor (1970). Though Shigella dysenteriae type I is known to elaborate a "neurotoxin" which causes paralysis in mice (McIver, 1975), we know of no data supporting shigella toxin induced seizures. Severe hyponatremia on hypoglycemia are not consistently demonstrated in patients with seizures and diarrhoea at the ICDDR,B hospital. Other CNS illness, such as bacterial meningitis, is reportedly rare in shigellosis (Barrett-Connor and connor, 1970).

Shigella bacteremia has been described as generally uncomplicated (Keusch, 1979). Recently, however, Duncan et al. (1981) found a surprising 7% incidence of shigella bacteremia/septicemia in shigella enteritis, with a mortality rate of 50%. Severe hypotension without apparent bacteremia also occurs. It has been proposed that this may be toxin medi- (Steisenger and Fordtran, 1978, p.1682).

Hypoglycemia is occasionally noted in children presenting to ICDDR,B hospital with diarrhoea of varying duration. In these patients, there seems to be no consistent relationship of hypoglycemia with malnutrition.

Other uncommon problems associated with shigellosis include cystitis and conjunctivitis, joint effusion, a post-shigellosis Reiter's syndrome, various skin lesions and metastatic infection in bone, joints, brain, lung, and spleen (Keusch, 1979).

3. Rationale:

Shigellosis is frequently accompanied by intestinal or extraintestinal complications. Early identification of patients at risk for complications may be useful to the clinician in helping to avert these complications. In addition, the incidence of many complications in patients hospitalized with shigellosis is unknown and should be determined.

B. SPECIFIC AIMS.

The specific aims are to identify the presenting clinical features, laboratory data, and hospital course (including complications) of shigella infection. This study will form the basis for a prospective clinical study of shigellosis in the near future.

C. METHODS OF PROCEDURE

Review of charts:

1. All hospitalized cases with shigella isolates from 1980 will be identified through microbiologic records. The corresponding case records (about 400 charts) will be analyzed.

2. Data collection: From these charts the required and available data will be recorded on data sheets (example attached) for entering onto computer discs.

   a. Historical data will include: age, sex, duration and severity of diarrhoea, duration of "fever," presence of convulsions, and intercurrent illness (e.g., recent measles).

   b. Admission physical examination data will include: pulse profile (normal, diminished, absent), temperature, severity of dehydration, degree of malnutrition, presence of bowel sounds or abdominal distension, seizures, and mental status.

c. Admission laboratory features to be recorded include: stool exam (macro and microscopic blood, number of leukocytes), hematocrit, presence of RBC fragmentation, white blood count, platelet count, shigella species, and antibiogram.

d. Morbidity will include a limited set of problems : prolonged hospitalization (>4 days), seizures in hospital, meningitis, pneumonitis, hemolytic anaemia, hemolytic-uremic syndrome, and severe colitis or peritonitis.

e. Outcome, including discharge, death and referral will be recorded.

3. Data analysis will take place in 2 parts:

a. The frequency of individual features (see II.C.2.a. to c.above) will be determined to help formulate a "clinical picture" of shigellosis.

b. A number of tables will be constructed through computer analysis to determine correlations between admission variable(s) (see II.C2a. to c. above) and subsequent morbidity or mortality (see II.C.2.d. to e. above). Examples of such tables are: age-adjusted mortality rates for hospitalized cases of shigellosis, presence of malnutrition vs. mortality, incidence of seizures, hemolytic anemia, and HUS for different shigella species, duration of diarrhea before admission vs. mortality, presence of fecal leukocytes vs. duration of hospitalization.

D. SIGNIFICANCE

Examination of charts in this retrospective analysis will provide valuable information on the clinical features and complications of shigellosis.

E. FACILITIES REQUIRED

No special facilities will be required.

REFERENCES

1. Hossain MMB, Glass RI, Huq MI and Yunus M - Five years surveillance of shigella among patients attending a hospital for diarrhoeal diseases in rural Bangladesh. ABS, presented at International Conference on Shigellosis, Cox's Bazar, 1980

2. Khan MU - Epidemiology of shigellosis. Manuscript, 1981

3. Curtis KJ, and Sleisenger MH - Infectious and parasitic diseases, chapter 105, in Gastro-intestinal Disease: Pathophysiology, Diagnosis, Management, 2nd edition. Ed. by MH Sleisenger and JS Fordtran. WB Saunders Co, Philadelphia, 1978: pp 1680-1684

4. Barrett-Connor E, and Connor JD - Extra-intestinal manifestation of shigellosis. Am. J. Castroenterol 53:234-245, 1970

5. Rahaman MM - Shiga bacillus dysentery associated with marked leukocytosis and erythrocyte fragmentation. Johns Hopkins Med J. 136:65-70, 1975

6. Koster F - Hemolytic-uremic syndrome after shigellosis. NEJM 298: 927-933, 1978

7. Knowlesson M and Forbes GB - The febrile convulsion in shigellosis. NEJM 258:520-526, 1958

8. McIver J, Grady GF, and Keusch GT - Production and characterization of exotoxin(s) of Shigella dysenteriae type I. J.I.D. 131: 559-569, 1975

9. Keusch GT - Shigella infections, in Clinics in Gastroenterology vol 8(3) Sept, 1979. Edt. by HP Lambert, WB Saunders Co, London, 1979, pp 645-662

10. Burris, J - Shigella sepsis. Am. J. Dis. Child 135:151-154

SECTION III - BUDGET

A. Personnel Services:

Name	Position	%Effort	Taka	Dollars
Dr. P. Speelman	Investigator	10	-	1,200
Dr. W. Brinton	Investigator	50 (1 mth.only)		375
Dr. I. Kabir	Investigator	25	5,000	
B. Xerox and Paper			-	100
C. Computer Time				
15 hours at Tk.1000/hr			15,000	
			20,000	1,675

Total US $2,675

(Conversion rate US $1 = Taka 20)

WB/mbs

SHIGELLA STUDY CHART REVIEW

Card No. / / (1)

Study No. / / / / (2 3 4)

HISTORY:

Hospital No. .... / / / / / / / (5 6 7 8 9 10)

Age (yr-mo): (99-99=NA) .... / / /-/ / / (11 12 13 14)

Sex (1=male,2=female,9=NA) .... / / (15)

Date adm (d-mo-yr) (99-99-99=NA) .... / / /-/ / /-/ / / (16 17 18 19 20 21)

Date disch (d-mo-yr) (99-99-99=NA) .... / / /-/ / /-/ / / (22 23 24 25 26 27)

Diarrhoea, total No.stools (00=no diarr, 98=>100 stools,99=NA) .... / / / (28 29)

Diarrhoea duration (days) (00=no diarr, 98=>100 days,99=NA) .... / / / (0 31)

Diarrhoea character (1=liquid/watery, 2=loose,3=soft,4=formed/nl,9=NA) .... a. / / (32)

(1=mucus, 2=blood, 3=1+2, 4= no mucus or blood, 8=NA) b. / / (33)

Vomiting,total No. (00=no vomiting 98=>100,99=NA) .... / / / (34 35)

Vomiting duration (days) (00=no vomit, 98=>100,99=NA) .... / / / (36 37)

Anorexia (1=no,2=yes,9=NA) .... / / (38)

Abd.pain/discomfort (1=both no, 2=either yes,9=NA) .... / / (39)

Fever (1=no,2=yes,9=NA) .... / / (40)

Fever duration (days) (00=no fever, 98=>100 days,99=NA) .... / / / (41 42)

Urine last passed(hrs) (99=NA) .... / / / (43 44)

Outside therapy: (0=none,1=Ampicillin, 2=Tetracycline,3=sulfa,septrin,bactrim, 4=Furoxone/Furazolidine,5=Adysin, 6=Enterfram/neomycin,7=other antibiotic _____ 8=other RX _____,9=NA) .... a. drug / / (45)

b. other drug / / (46)

(0=none,1=IV,2=ORS,3=po fluids besides ORS,4=1+2,5=2+3,6=1+3,7=1+2+3, 9=NA) c. Fluids / / (47)

.../2

Dietary History (A=breast milk, B=other milk/formula, C=barley salt, D=adult food, E=A+B, F=A+C, G=A+D, H=B+C, J=B+D, K=C+D, L=A+B+C, M=A+B+D, N=A+C+D, P=B+C+D, Q=A+B+C+D, R=other _____ .... / 48

other _____
X=water only, Y=no food/water, Z=NA)

ADDITIONAL HISTORY

Tenesmus (1=no, 2=yes, 9=NA) .... / 49

Cough duration (days) (00=no cough, 97=cough but duration not specified 98=>100 days, 99=NA) .... / / / 50 51

Shortness of breath (dyspnea) (1=no, 2=yes, 9=NA) .... / 52

Mental status (1=nl, 2=sleepy/lethargic, 3=irritable, 4=comatose/unresponsive, 5=delirious, 6=restless/agitated 8=other, 9=NA) .... a. / 53 b. / 54

Recent seizures (no.) (0=none, 8=>7, 9=NA) .... / 55

Recent seizures duration (hrs.) (00=no seizure, 98=>100 hrs. 99=NA) .... / / / 56 57

Past history of seizures (1=no, 2=yes, 9=NA) .... / 58

Recent measles (no. days ago) (00=no measles, 97=recent measles but time not specified, 98=>100 days ago, 99=NA) .... / / / 59 60

Other important history _____

_____

Past history _____

_____

SHIGELLA STUDY CHART REVIEW

Card No. /2/ (1)

Study No. /_/_/_/_/ (2 3 4)

PHYSICAL EXAM

Radial pulse rate (000=pulseless, 999=NA) .... /_/_/_/ (5 6 7)

Radial pulse quality (0=pulseless, 1=weak, 2=nl, 3=other, 9=NA) .... /_/ (8)

Respiration rate (00=no resp, 99=NA) .... /_/_/ (9 10)

Respiration quality (0=no resp, 1=gasp, 2=deep, 3=shallow, 4=nl, 5=other _____, 9=NA) .... /_/ (11)

Temperature site (1=oral, 2=axillary, 3=rectal, 9=NA) .... /_/ (12)

Temp of (999.9=NA) .... /_/_/_/_/ (13 14 15 16)

Nutrition (1=obese, 2=nl, 3=thin, 4=malnourished, 9=NA) .... /_/ (17)

Pallor (1=no, 2=yes, 9=NA) .... /_/ (18)

Cyanosis (1=no, 2=yes, 9=NA) .... /_/ (19)

Edema (1=no, 2=yes, 9=NA) .... /_/ (20)

Jaundice (1=no, 2=yes, 9=NA) .... /_/ (21)

Abdominal tenderness (1=no, 2=yes, 9=NA) .... /_/ (22)

Abdominal mass (1=no, 2=yes, 9=NA) .... /_/ (23)

Abdominal distension (1=no, 2=yes, 9=NA) .... /_/ (24)

Liver (1=not palpable, 2=palpable, 3=other _____, 9=NA) .... /_/ (25)

Bowel sounds (0=none/absent, 1=nl/present, 2=decreased/hypoactive, 4=other _____, 3=increased/hyperactive, 9=NA) .... /_/ (26)

Breath sounds (1=nl, 2=bronchial, 3=vesicular, 4=decreased, 5=other _____, 9=NA) .... /_/ (27)

Rales (1=no, 2=yes, 3=NA) .... /_/ (28)

Rhonchi (1=no, 2=yes, 3=NA) .... /_/ (29)

Mental Status (1=nl/conscious, 2=poorly responsive/semiconscious, 3=irritable, 4=restless, 5=lethargic, 6=obtunded, 7=comatose/unresponsive, 8=other _____, 9=NA) .... a. /_/ (30) b. /_/ (31)

Pupils (1=nl, 2=dilated, 3=constricted, 4=asymmetric, 5=other _____, 9=NA) .... /_/ (32)

.../4

Conjunctiva (1=nl,2=injected/conjunctivitis 3=Bitot's spots,4=other _____,9=NA) .... / / 33

Ears (1=nl,2=abnl, 9=NA) .... / / 34

Rectal prolapse (1=no,2=yes, ?=NA) .... / / 35

Dehydration (0=none,1=mild,2=mild-mod, 3=moderate,4=mod-severe,5=severe, 6=yes,7=other_____,9=NA) .... / / 36

Other physical findings: _____

_____

_____

DIAGNOSIS AND SUMMARY

Diarrhoea (1=no,2=yes,9=NA) .... / / 37

Shigellosis (1=no,2=yes,9=NA) .... / / 38

Bronchopneumonia/pneumonia (1=no,2=yes,9=NA) .... / / 39

Measles/post-measles (1=no,2=yes,9=NA) .... / / 40

Electrolyte imbalance (1=no,2=yes,9=NA) .... / / 41

Enteric Fever (1=no,2=yes,9=NA) .... / / 42

GI bleed/Hemorrhage (1=no,2=yes,9=NA) .... / / 43

Bowel perforation (1=no,2=yes,9=NA) .... / / 44

Vitamin deficiency (1=no,2=yes,9=NA) .... / / 45

Meningitis (1=no,2=yes,9=NA) .... / / 46

"Sepsis" (1=no,2=yes,9=NA) .... / / 47

Malaria (1=no,2=yes,9=NA) .... / / 48

Malnutrition (1=no,2=yes,3=mild, 4=mild/mod,5=mod,6=mod/seve, 7=severe,9=NA) .... / / 49

Other _____ .... / / 50

Other _____ .... / / 51

Other _____ .... / / 52

SHIGELLA STUDY CHART REVIEW

LABORATORY

Card No. 131 / 1

Study No. / / / / (1 2 3 4)

Faeces Exam

		Day	Day	Day
Hospital day	.....	/ / / (5 6)	/ / / (30 31)	/ / / (55 56)
Consistency (1=liquid/watery, 2=loose 3=soft, 4=formed, 9=NA)	.....	/ / (7)	/ / (32)	/ / (57)
pH (1=acid, 2=alkaline, 9=NA)	.....	/ / (8)	/ / (33)	/ / (58)
Blood (0=none, 1=present, 2=other _____, 9=NA)	.....	/ / (9)	/ / (34)	/ / (59)
Mucus (0=none, 1=present, 2=other _____, 9=NA)	.....	/ / (10)	/ / (35)	/ / (60)
Guiaic (0=negative, 1=1+, 2=2+, 3=3+, 4=4+, 5=positive, 6=trace+, 7=other _____, 9=NA)	.....	/ / (11)	/ / (36)	/ / (61)
Protozoa veg: (0=none/other, 1=Giardia, 2=E.his, 3=E.hist with RBC phago, 4=1+2, 5=1+3, 6=2+3, 7=1+2+3, 9=NA)	.....	/ / (12)	/ / (37)	/ / (62)
Protozoa cysts: (0=none/other, 1=Giar, 2=E.hist, 3=1+2, 9=NA)	.....	/ / (13)	/ / (38)	/ / (63)
Pus cells + macrophages No.(avg) (998=>1000, 999=NA)	.....	/ / / (14 15 16)	/ / / (39 40 41)	/ / / (64 65 66)
RBC. No.(avg) (99=NA)	.....	/ / (17 18)	/ / (42 43)	/ / (67 68)

Urine Physical Exam:

		Day	Day	Day
Hospital day	.....	/ / / (19 20)	/ / / (44 45)	/ / / (69 70)
Color (1=pink/red/bloody 2=other _____, 9=NA)	.....	/ / (21)	/ / (46)	/ / (71)
Albumin (0=negat, 1=1+, 2=2+, 3=3+, 4=4+, 5=positive, 6=other _____, 9=NA)	....	/ / (22)	/ / (47)	/ / (72)

Urine Micro Exam:

Pus cells No.(avg) (98=>100, 99=NA)	.....	/ / / (23 24)	/ / / (48 49)	/ / / (73 74)
R B C No.(avg) (98=>100, 99=NA)	.....	/ / / (25 26)	/ / / (50 51)	/ / / (75 76)
Epith cells No. (avg) (8=>7, 9=NA)	.....	/ / (27)	/ / (52)	/ / (77)
Cast type (0=neither WBC nor RBC, 1=WBC casts, 2=RBC casts, 3=1+2, 9=NA)	.....	/ / (28)	/ / (53)	/ / (78)
Bacteria (0=none, 1=1+, 2=2+, 3=3+, 4=4+, 9=NA)	.....	/ / (29)	/ / (54)	/ / (79)

SHIGELLA STUDY CHART REVIEW

LABORATORY

Card No. 141 / 1

Study No. 1 1 1 1 / 2 3 4

Blood Report:

		Day	Day	Day
Hosp day	.....	5 6	28 29	51 52
ESR: a) obs (98=>100, 99=NA)	.....	7 8	30 31	53 54
b) corr (98=>100, 99=NA)	.....	9 10	32 33	55 56
Hct % (99=NA)	.....	11 12	34 35	57 58
Polychrom (1=1+, 2=2+, 3=3+, 4=4+, 5=other_____, 9=NA)		13	36	59
Fragmentation (0=none, 1=1+, 2=2+, 3=3+, 4=4+, 5=other_____, 9=NA)		14	37	60
Nucleated RBC No/100 (0=none, 8=>7, 9=NA)		15	38	61
T.W.B.C. x 1000 (999=NA)	.....	16 17 18	39 40 41	62 63 64
Polys % (99=NA)	.....	19 20	42 43	65 66
Bands % (99=NA)	.....	21 22	44 45	67 68
Platelets x 1000 (999=NA) (996=decreased, 997=increased, 998=normal)	.....	23 24 25	46 47 48	69 70 71
Reticulocytes (nearest %) (99=NA)	.....	26 27	[illegible]	72 73

Card No. 151 / 1

Study No. 1 1 1 1 / 2 3 4

Clincial Chemistry:

		Day	Day	Day	Day
Hosp day	.....	5 6	28 29	46 47	68 69
Glucose (99.9=NA)	.....	7 8 . 9 10	31 32 . 33		
Urea (99=NA)	.....	10 11	34 35	47 52	68 69
Creatinine (999=NA)	.....	12 13 14	36 37 38	53 54 55	70 71 72
Na^+ (999=NA)	.....	15 16 17	39 40 41	56 57 58	
Cl (999=NA)	.....	18 19 20	42 43 44	59 60 61	
K^+ (9.9=NA)	.....	21 . 22	45 . 46	62 . 63	73 . 74
Tco_2 (99=NA)	.....	23 24	47 48	64 65	75 76
Sp.Gr. (9.999=NA)	.....	25 . 26 27 28			

SHIGELLA STUDY CHART REVIEW

Card No. 151 / 1

Study No. / / / / (2 3 4)

LABORATORY

Culture Results

A. Stool culture:

		Day	Day	Day
1. Hosp day (99=not done)		/ / (5 6)	/ / (14 15)	/ / (23 24)
2. Species of shigella (1=dysent, 2=dysent. type 1 (shiga), 3=flexn, 4=boydi, 5=sonnei, 6=schmitt, 7=other _____)		/ / (7)	/ / (16)	/ / (25)
3. Antibiotic sensitivity: Tetracycline (1=sensit, 2=resistant, 3=intermediate, 9=NA)		/ / (8)	/ / (17)	/ / (26)
Ampicillin (1=sensit, 2=resistant, 3=intermediate, 9=NA)		/ / (9)	/ / (18)	/ / (27)
Chloramphenicol (1=sensit, 2=resist, 3=intermediate, 9=NA)		/ / (10)	/ / (19)	/ / (28)
Gentamicin (1=sensit, 2=resist, 3=intermediate, 9=NA)		/ / (11)	/ / (20)	/ / (29)
Trimethoprim-sulfa (1=sensit, 2=resist, 3=interm, 9=NA)		/ / (12)	/ / (21)	/ / (30)
4. Other stool pathogens (1=Vibrio chole, 2=NAG vibrio, 3=campylob, 4=salmon typhi, 5=other salmon, 6=ETEC/EPEC (E.coli) 7=staph aureus, 9=NA) 8=other _____		/ / (13)	/ / (22)	/ / (31)

B. Other Cultures:

* A=Bacteroides, B=Campylobacter, C=Clostridia, D=Enterobacter, E=E.coli, F=Hemophilus influenzae, G=Klensiella, H=Neisseria meningitidis, I=Proteus, J=Pseudomonas, K=Salmonellatyphi, L=other Salmonella, M=Staph aureus, N=Staphepidermidis, P=Strep Gr.A, Q=Strep Gr.B, R=Strep Gr.D/Strep Faecalis, S=strep pheumoniae/Diplococcus, T=other strep, U=Vib cholerae, V=other Vibrio, W=others _____, X=normal flora, Y=mixed or several orgs _____, Z=no growth

		Day	Day
1. Urine culture			
Hosp day (99=not done)		/ / (32 33)	/ / (36 37)
No.of colonies (1=>100,000 2=10,000-100,000 3=<10,000, 9=NA)		/ / (34)	/ / (38)
*Culture result (9=NA)		/ / (35)	/ / (39)
2. Blood culture		Day	Day
Hosp day (99=not done)		/ / (40 41)	/ / (43 44)
*Culture result (9=NA)		/ / (42)	/ / (45)

3. Sputum culture

		Day	Day
Hosp day (99=not done)	.....	46 47	50 51
*Result: (Predominant organism) (9=NA)	.....	48	52
*Other organisms (9=NA)	.....	49	53

4. CSF culture

		Day	Day
Hosp day (99=not done)	.....	54 55	57 58
*Result (9=NA)	.....	56	59

Stool Darkfield Exam

		Day	Day
Hosp day (99=NA)	.....	60 61	63 64
D/F (D or ∈) (1=positive, 2=negative, 9=NA)	.....	62	65

Card No. 16 / 1

Study No. 2 3 4

CLINICAL RECORD

Respiration - abnormal values:
(0 to 1 mo=>50, 1 mo to 2 yr=>40, 2 to 10 yr=>30, >10 yr=>20)

			Day	Day
Onset of abnormal daily mean resp (00=nl, 99=NA)	.....		5 6	34 35
Duration of abnormal daily mean resp (00=nl, 99=NA)	.....	(days)	7 8	36 37

Pulse - abnormal values:
(0 to 1 mo=>160, 1 mo to 2 yr=>150, 2 to 10 yr=>130, 10 yr=>100)

			Day	Day
Onset of abnormal daily mean pulse (00=nl, 99=NA)	.....		9 10	38 39
Duration of abnormal daily mean pulse (00=nl, 99=NA)	.....	(days)	11 12	40 41

Temperature

Maximum temp during hospitalization (999.9=NA)	.....	13 14 15 . 16
Day on which max temp occurred (99=NA)	.....	Day 17 18

		Day	Day
Maxi daily temp > 100°F: day onset (No) (00=None, 44=NA)	.....	19 20	42 43
duration (days) (00=none, 99=NA)	.....	21 22	44 45
Mean daily temp >100°F: day onset No.) (00=none, 99=NA)	.....	23 24	46 47
duration days (00=none, 99=NA)	.....	25 26	48 49

Systolic Blood Pressure - record only if systo <80/>150)

		Day	Day
Day recorded (00=no, 99=NA) BP<80/>150	.....	27 28	50 51
BP systolic (000=no, 999=NA) BP<80/>150	.....	29 30 31	52 53 54
Consecutive days (No.) (00=no, 999=NA) of BP<80/>150	.....	32 33	55 56

Medications

#1 #2 #3 #4
57 63 69 75

(00=none, A=Amp, B=Carb, C=Chloram, D=Chloroq, E=Erythro, F=Furaz, G=Gent, Kana, Strep, H=INH, I=Metro, J=Neomyc, K=Nyst, L=Pen, M=PRPen, N=Quinacrine, P=Sulfa, R=Sulf-trim, S=Tetra, T=other antibi_____, U=other antib_____, V=Aspir, W=Paracet, X=glucocorticosteroids, Y=other _____, Z=other_____)

	Day	Day	Day	Day
Day started (00=not given, 99=NA)	58 59	64 65	70 71	76 77
Days given (00=not given, 99=NA)	60 61	66 67	72 73	77 78
Route (1=IV, 2=IM, 3=po, 4=other, 9=NA)	62	68	74	79

Other medicine (including day started - day given):

_____

_____

Card No. 171

Study No. 3 5 4

Height (mm) (9999=NA) 5 6 7 8

Weight (kg)- after 1st day preferably (99=NA) 9 10

Diet

1. NPO

	Day	Day
started (day No.) (00=not started 99=NA)	11 12	43 44
duration (days) (" " ")	13 14	45 46

2. liquids or solid food

	Day	Day
started (day No.) (00=not started, 99=NA)	15 16	47 48
duration (days) (" ")	17 18	49 50

IV Fluids

	Day	Day
started (day No.) (00=not started, 99=NA)	19 20	51 52
duration (days) (" " ")	21 22	53 54

Stool volume - record only if >400 cc/day

	Day	Day
onset (day No.) (00=<400, 99=NA)	23 24	55 56
duration (days) (" " ")	25 26	57 58

Urine volume - record only if <200 cc/day

	Day	Day
onset (day No.) (00=not <200 cc, 99=NA)	27 28	59 60
duration (days) (" " " " ")	29 30	61 62

Vomiting

	Day	Day
onset (day No.) (00=no vomit, 99=NA)	31 32	63 64
duration (days) (" " ")	33 34	65 66

Stool consistency - record only if loose or watery

	Day	Day
onset (day No.) (00=No diarr, 99=NA)	35 36	67 68
duration (days) (" " ")	37 38	69 70

Stool color- record only if bloody red, etc. .....

	Day	Day
onset bloody stools (day No.) (00=no blood, 99=NA)	39 40	71 72
duration bloody stools (" " ")	41 42	73 74

SHIGELLA STUDY CHART REVIEW

Card No. 1 8 / 1

Study No. / / / /
2 3 4

GRESS NOTES, COMPLICATIONS

trointestinal hemorrhage, onset (day No.) / / /
(00=no hemorrhage, 99=hemorrh., but onset NA) 5 6

od type (1=A+, 2=A-, 3=B+, 4=B-, 5=AB+, 6=AB-, / /
7=O+, 8=O-, 9=NA) 7

ts of blood transfused (No.) / /
(0=none, 8=>7 units, 9= blood given, but No. NA) 8

od transfusion, onset (day No.) / / /
(00=no transfusion, 99=blood given, but day NA) 9 10

onged absence of bowel sounds:

Onset (day No.) / /
(0=no absence noted, 8=>day 7, 9=BS absent, but onset NA) 11

Duration (days) / /
(0=no absence noted, 8=>7 days, 9= BS absent, but dur. NA) 12

sistent abdominal distension

Onset (day No.) / /
(0=no dist. noted, 8=>day 7, 9=distension, but onset NA) 13

Duration (days) / /
(0=no dist. noted, 8=>7days, 9=distension, but dur. NA) 14

gacolon," onset (day No.) / /
(0=no megacolon noted, 8=>day 7, 9= megacolon, but onset NA) 15

el perforation, or peritonitis, onset (day No.) / /
(0=none noted, 8=>day 7, 9=did occur, but onset NA) 16

ominal abscess, onset (day No.) / /
(0=no abscess, 8=>day 7, 9=abscess, but onset NA) 17

tal prolapse, duration (days) / /
(0=no prolapse noted, 8=>7 days, 9=prolapse, but dur. NA) 18

ration required (1=yes, 2=no, 9=NA) / /
19

zure noted after admission:

	Sz. A	Sz. B
Onset (day No.) (0=no sz. noted, 8=>day 7, 9=sz., but day NA)	/ / 20	/ / 90
No. of seizures (0=none, 8=>7, 9=seizures, but No. NA0)	/ / 21	/ / 91
No. of days seizures noted (0=no sz. noted, 8=>7days, 9=sz. noted, but dur. NA)	/ / 22	/ / 92
Temperature prior to any seizure (°F) (000.0=no sz. noted, 999.9=sz. noted, but temp. NA)	/ / / . / / 23 24 25 26	/ / / . / / 43 44 45 46
Time before seizure temp. taken (hrs.) (0=no sz. noted, 8=>7 hours, 9=sz. noted, but time NA)	/ / 27	/ / 47
Blood glucose before seizure (same day) (00.0=no sz. noted, 99.9=sz. noted, but no glucose before)	/ / . / / 28 29 30	/ / . / / 48 49 50
Blood glucose after seizure (00.0=no sz., 99.9=sz., but no gluc.)	/ / . / / 31 32 33	/ / . / / 51 52 53
Na before seizure (000= no sz., 999=no Na before sz.)	/ / / / 34 35 36	/ / / / 54 55 56
Na after seizure (000=no sz., 999=no Na after sz.)	/ / / / 37 38 39	/ / / / 57 58

Altered mental status:

Onset (day No.)
(0=no altered MS noted, 8=>day 7, 9= altered MS, but day NA) / / 60

Duration (days)
(00=no altered MS noted, 99=altered MS noted, but dur. NA) / / / 61 62

"Pneumonia" onset (day No.)
(0=no pneumonia noted, 8=>day 7, 9=pneum. noted but day NA) / / 63

Hemolytic anemia or hemolysis, onset (day No.)
(00=neither noted, 99=either noted, but day NA) / / / 64 65

"Oliguria", onset (day No.)
(00=oliguria not noted, 99=oliguria noted, but day NA) / / / 66 67

Hemolytic-uremic syndrome (HUS), onset (day No.)
(00=HUS not noted, 99=HUS noted, but day NA) / / / 68 69

Meningitis, onset (day No.)
(0=meningitis not noted, 8=>day 7, 9=meningitis noted but day NA) / / 70

Arthritis or joint effusion, onset (day No.)
(0=neither noted, 8=>day 7, 9= either noted, but day NA) / / 71

Outcome (1=discharge, 2=dead, 3=referred,
4=discharge on risk bond, 9=NA) / / 72