Implementation Manual

Part 3 of 3: Appendices (Pages 63 – 97)

Completion of Electronic Case Report Forms

This study is registered at Clinicaltrials.gov.
Identification number NCT00133978
Appendix 1
Randomization Process on Web

Screen New Subject
“Only Subjects Who Meet Inclusion Criteria”

Screening Form Inclusion/Exclusion

Meets an Exclusion Ends

No Exclusion Eligible for Study

Pre Randomization Form
Eligibility Must Be Confirmed By MD

Do you obtain consent?

Yes

- Consent Obtained
- Subject’s Height in cm.
- CLICK here to Randomize Patient button

Subject is now Randomized
Enrollment Number Is____

- Contact your Site Pharmacy and enter date and time of contact.
- Provide Height/Subject Initials/DOB/Enrollment Number

After Randomization
Study Coordinator Expected to Complete Baseline Form & APACHE Score and other Electronic CRFs

Pharmacist Receives call from Study Coordinator

Pharmacist Logs onto Web

Pharmacist Receives
- Treatment Assignment
- Subject’s Initials
- Date of Birth
- Height
# Appendix 2

## Height Conversion Table

One foot = 12 inches  
One inch = 2.54 cms

<table>
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<tr>
<th>Feet/Inches</th>
<th>Inches</th>
<th>Centimeters</th>
<th>Feet/Inches</th>
<th>Inches</th>
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<td>54</td>
<td>137</td>
<td>5ft 10 inch</td>
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<tr>
<td>4ft 7 inch</td>
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<td>140</td>
<td>5ft 11 inch</td>
<td>71</td>
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<td>73</td>
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<tr>
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<td>58</td>
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<td>74</td>
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<tr>
<td>4ft 11 inch</td>
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<td>6ft 3 inch</td>
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<td>76</td>
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<tr>
<td>5ft 1 inch</td>
<td>61</td>
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<td>5ft 8 inch</td>
<td>68</td>
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<td>7 ft</td>
<td>84</td>
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<tr>
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<td>69</td>
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<td>7ft 1 inch</td>
<td>85</td>
<td>216</td>
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</tbody>
</table>
Appendix 3
ICU Admission Diagnosis Taxonomy

NON-OPERATIVE CONDITIONS
Choose from this list if admission category is medical

Cardiovascular / vascular:
1. □ Cardiogenic shock
2. □ Cardiac arrest
3. □ Aortic aneurysm
4. □ Congestive heart failure
5. □ Peripheral vascular disease
6. □ Rhythm disturbance
7. □ Acute myocardial infarction
8. □ Hypertension
9. □ Other CV disease: __________

Respiratory:
10. □ Parasitic pneumonia (ie.pneumocystis carinii)
11. □ Aspiration pneumonia
12. □ Respiratory neoplasm (inc. larynx, trachea)
13. □ Respiratory arrest
14. □ Pulmonary edema (non-cardiogenic)
15. □ Bacterial / Viral pneumonia
16. □ Chronic obstructive pulmonary disease
17. □ Pulmonary embolism
18. □ Mechanical airway obstruction
19. □ Asthma
20. □ Other respiratory disease: __________

Gastrointestinal:
21. □ Hepatic failure
22. □ GI perforation/obstruction
23. □ GI bleeding due to varices
24. □ GI inflammatory disease (ulcerative colitis, crohn’s disease)
25. □ GI bleeding due to ulcer/laceration
26. □ GI bleeding due to diverticulosis
27. □ Pancreatitis
28. □ Other GI disease: __________

Neurologic:
29. □ Intracerebral hemorrhage
30. □ Subarachnoid hemorrhage
31. □ Stroke
32. □ Neurologic infection
33. □ Neurologic neoplasm
34. □ Neuromuscular disease
35. □ Seizure
36. □ Other neurologic disease: __________

Sepsis:
37. □ Sepsis (other than urinary tract)
38. □ Sepsis of urinary tract origin

Trauma:
39. □ Head trauma (with/without multiple trauma)
40. □ Multiple trauma (excluding head trauma)

Metabolic:
41. □ Metabolic coma
42. □ Diabetic ketoacidosis
43. □ Drug overdose
44. □ Other metabolic disease: __________

Hematologic:
45. □ Coagulopathy /neutropeniathrombocytopenia
46. □ Other hematologic condition: __________

Other:
47. □ Renal disease: __________
48. □ Burns
49. □ Other medical disease: __________

POST-OPERATIVE CONDITIONS:
Choose from this list if admission category is surgical

Vascular / cardiovascular:
50. □ Dissecting/ruptured aorta
51. □ Peripheral vascular surgery (no bypass graft)
52. □ Valvular heart surgery/CABG
53. □ Elective abdominal aneurysm repair
54. □ Peripheral artery bypass graft
55. □ Carotid endarterectomy
56. □ Other CV disease: __________

Respiratory:
57. □ Respiratory infection
58. □ Lung neoplasm
59. □ Respiratory neoplasm (mouth, sinus, larynx, trachea)
60. □ Other respiratory disease: __________

Gastrointestinal:
61. □ GI perforation/rupture
62. □ GI inflammatory disease
63. □ GI obstruction
64. □ GI bleeding
65. □ Pancreatitis
66. □ Liver transplant
67. □ GI neoplasm
68. □ GI cholecystitis / cholangitis
69. □ Other GI disease: __________

Neurologic:
70. □ Intracerebral hemorrhage
71. □ Subdural/epidural hematoma
72. □ Subarachnoid hemorrhage
73. □ Laminectomy/other spinal cord surgery
74. □ Craniotomy for neoplasm
75. □ Other neurologic disease: __________

Trauma:
76. □ Head trauma (with/without multiple trauma)
77. □ Multiple trauma (excluding head trauma)

Renal:
78. □ Renal neoplasm
79. □ Other renal disease: __________

Gynecologic:
80. □ Hysterectomy

Orthopedic:
81. □ Hip or extremity fracture

Bariatric Surgery:
82. □ Laparoscopic Banding
83. □ Laparoscopic Gastric Bypass
84. □ Open Gastric Bypass (Roux-en-Y)
85. □ Vertical Banded Gastropasty

Other:
86. □ Other surgical condition: __________
Appendix 4
Comorbid Taxonomy

0. □ NONE

### MYOCARDIAL
1. □ Angina
2. □ Arrhythmia
3. □ Valvular
4. □ Myocardial infarction
5. □ Congestive heart failure (or heart disease)

### VASCULAR
6. □ Hypertension
7. □ Peripheral vascular disease or claudication
8. □ Cerebrovascular disease

### PULMONARY
9. □ Chronic obstructive pulmonary disease (COPD, emphysema)
10. □ Asthma

### NEUROLOGIC
11. □ Dementia
12. □ Hemiplegia (paraplegia)
13. □ Stroke or TIA
14. □ Neurologic illnesses (such as Multiple sclerosis or Parkinsons)

### ENDOCRINE
15. □ Diabetes Type I or II
16. □ Diabetes with end organ damage
17. □ Obesity and/or BMI > 30 (weight in kg/(ht in meters)^2

### RENAL
18. □ Moderate or severe renal disease

### GASTROINTESTINAL
19. □ Mild liver disease
20. □ Moderate or severe liver disease
21. □ GI Bleeding
22. □ Inflammatory bowel
23. □ Peptic ulcer disease
24. □ Gastrointestinal Disease (hernia, reflux)

### CANCER/IMMUNE
25. □ Any Tumor
26. □ Lymphoma
27. □ Leukemia
28. □ AIDS
29. □ Metastatic solid tumor

### PSYCHOLOGICAL
30. □ Anxiety or Panic Disorders
31. □ Depression

### MUSKOSKELETAL
32. □ Arthritis (Rheumatoid or Osteoarthritis)
33. □ Degenerative Disc disease (back disease, spinal stenosis or severe chronic back pain)
34. □ Osteoporosis
35. □ Connective Tissue disease

### MISCELLANEOUS
36. □ Visual Impairment (cataracts, glaucoma, macular degeneration
37. □ Hearing Impairment (very hard of hearing even with hearing aids)
### Appendix 5
Formula Taxonomy

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<th>Formula Name</th>
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<td>NOVARTIS: Vivonex TEN</td>
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<tr>
<td>NESTLE: Peptamen with Prebio 1</td>
<td>NOVARTIS: Vivonex Plus</td>
</tr>
<tr>
<td>NESTLE: Peptamen</td>
<td>NOVARTIS: Supplements-Instant</td>
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<tr>
<td>NESTLE: Peptamen 1.5</td>
<td>Protein Powder</td>
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<tr>
<td>NESTLE: Peptamen VHP</td>
<td>NOVARTIS: Supplements-Microlipid</td>
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<td>NESTLE: Peptamen AF</td>
<td>NOVARTIS: Supplements-MCT oil</td>
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<td>NESTLE: Nutren 2.0</td>
<td>NOVARTIS: Supplements-Res MCT</td>
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<tr>
<td>NESTLE: Nutren 1.5</td>
<td>Glutasolve</td>
</tr>
<tr>
<td>NESTLE: Nutren VHP</td>
<td>ROSS: Jevity 1 kcal</td>
</tr>
<tr>
<td>NESTLE: Nutren VHP fibre</td>
<td>ROSS: Jevity 1.2 kcal</td>
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<td>NESTLE: Nutren Fibre with Prebio 1</td>
<td>ROSS: Osmolite HN Plus</td>
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<td>ROSS: Osmolite HN</td>
</tr>
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<td>NESTLE: Nutrihep</td>
<td>ROSS: Promote</td>
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<td>NESTLE: Supplements - Caloreen</td>
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<td>NOVARTIS: Impact</td>
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<td>ROSS: Perative</td>
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<td>ROSS: Vital HN</td>
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<tr>
<td>NOVARTIS: Isosource HN with fibre</td>
<td>ROSS: TWO Cal HN</td>
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<td>ROSS: Ensure Fibre</td>
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<td>NOVARTIS: Resource Plus</td>
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## Appendix 6
### Organism Taxonomy

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<td>3 Acinetobacter sp.</td>
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<td>3b Other specify</td>
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<tr>
<td>4 Actinomyces sp.</td>
<td>4a Other specify</td>
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<tr>
<td>5 Aeromonas sp.</td>
<td>5a Aerogenea</td>
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<td>6b Foecalis</td>
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<td>7 Bacillus sp.</td>
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<td>8b Thetaiotamiron</td>
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<td>13c Pseudomallei</td>
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<td>18b Difficile</td>
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<td>18c Perfringes</td>
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<td>18d Tetani</td>
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<td>69</td>
<td>Hepatitis sp.</td>
</tr>
<tr>
<td>70</td>
<td>Influenza</td>
</tr>
<tr>
<td>71</td>
<td>Other Virus specify</td>
</tr>
<tr>
<td>72</td>
<td>Avium-Intracellular (MAI)</td>
</tr>
<tr>
<td>73</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>74</td>
<td>Other Mycobacteria specify</td>
</tr>
</tbody>
</table>
# Appendix 7
## Antibiotic Taxonomy

Appendix 8.1
Algorithm for ICU Acquired Infection Adjudication

*To be determined by the Site Investigator after review of Infection Adjudication Form and patient’s chart*

Was this culture or the prescription of this antibiotic for a NEW ICU acquired infection? (after 72 hours of admission from ICU admission)?

Yes

Choose the appropriate Categories of Infection (1-12)* and if:
Definite Yes or Probable Yes or Possible Yes

No

NO, because it is related to an infection previously diagnosed and adjudicated.

Possible** NO

END

Probable** NO

END

NO, because it is NOT an infection

* See Appendix 8.2 for categories and definitions of YES
** See appendix 8.3 for definitions of NO
Appendix 8.2
Categories of Infection

This document outlines the various categories of infection that may be considered “outcomes” in a clinical trial. We have attempted to operationalize the definitions developed by the International Sepsis Forum Consensus Conference (CCM 2005:33:1538-1548) and in doing so, have had to make some modifications to those definitions. Furthermore, given the uncertainty around the diagnosis of infection, we have consistently used the terminology, ‘Definite’ (a), ‘Probable’ (b), and ‘Possible’ (c) for each type of infection. The categories of infection include:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Deep surgical wound infection</td>
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<tr>
<td>2</td>
<td>Incisional (or superficial) surgical wound infection</td>
</tr>
<tr>
<td>3</td>
<td>Skin and soft-tissue infection (non-surgical) (SSTS)</td>
</tr>
<tr>
<td>4</td>
<td>Catheter-related blood stream infections (CRI)</td>
</tr>
<tr>
<td>5</td>
<td>Primary blood stream infections (BSI)</td>
</tr>
<tr>
<td>6</td>
<td>Lower urinary tract infection</td>
</tr>
<tr>
<td>7</td>
<td>Upper urinary tract infection</td>
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<tr>
<td>8</td>
<td>Intra abdominal infection</td>
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<tr>
<td>9</td>
<td>Sinusitis</td>
</tr>
<tr>
<td>10</td>
<td>Lower respiratory tract infection (excluding pneumonia)</td>
</tr>
<tr>
<td>11</td>
<td>ICU Acquired Pneumonia</td>
</tr>
<tr>
<td>12</td>
<td>Other</td>
</tr>
</tbody>
</table>
Category 1

**Deep surgical wound infection** must meet the following criterion:

Infection occurs at operative site within 30 days after surgery if no implant is left in place or within 1 year if implant is in place **AND** infection appears related to surgery **AND** infection involves tissues or spaces at or beneath fascial layer or a deeper anatomical space opened during the surgical procedure. In all categories, signs and symptoms suggestive of surgical site infection must be present. These include wound erythema and blanching, tenderness, pain, purulent discharge, fever, and leukocytosis.

a) **Definite Infection**

An abscess or other evidence of infection seen on direct examination, during surgery or by histopathologic examination.

**OR**

Organism isolated from culture of fluid obtained during open procedure or aspiration

b) **Probable Infection**

Purulent drainage from drain placed beneath fascial layer (no microbial confirmation or Gram stain positive but negative culture).

c) **Possible Infection**

Wound spontaneously dehisces or is deliberately opened by surgeon (no pus nor microbial confirmation).

Comments:

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Category 2

**Incisional (or superficial) surgical wound infection** must meet the following criterion:

Infection occurs at incision site within 30 days after surgery **AND** involves skin and subcutaneous tissue above the fascial layer. In all categories, signs and symptoms suggestive of surgical site infection must be present. These include wound erythema and blanching, tenderness, pain, purulent discharge, fever, and leukocytosis.

a) **Definite Infection**

Organism(s) isolated from culture of fluid from wound closed primarily

b) **Probable Infection**

Purulent drainage from incision or drain located above fascial layer (no microbial confirmation or Gram stain positive but no positive culture).

c) **Possible Infection**

Surgeon deliberately opens wound

Comments:

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Category 3

Skin and soft tissue infection (non-surgical) must meet the following criterion:

Infection occurs in skin or soft tissue structures (SSTS) NOT associated with surgical procedures.

a) Definite Infection
Compelling clinical and laboratory evidence (such as spreading cutaneous erythema and blanching, or drainage or purulent material, with or without lymphangitis, in association with fever and leukocytosis) of the presence of SSTS infection based on clinical, radiographic, or surgical findings

AND
Organism isolated from culture from a skin lesion that has drained pus or from a skin aspirate or biopsy of subcutaneous tissues of an erythematous skin lesion (not a simple skin swab).

b) Probable Infection
Compelling clinical and laboratory evidence (such as spreading cutaneous erythema and blanching, or drainage or purulent material, with or without lymphangitis, in association with fever and leukocytosis) or the presence of SSTS infection based on clinical, radiographic, or surgical findings

AND
No microbial confirmation or only positive Gram stain but negative culture.

c) Possible Infection
Some clinical evidence of infection, such as mild cutaneous erythema associated with fever, some laboratory evidence (leukocytosis), some radiographic but insufficient evidence to confirm a diagnosis.

AND
No microbial confirmation

Comments:
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Category 4

Catheter-related blood stream infections (CRI) must be associated with an indwelling central line (usually placed more than 5-7 days ago) and have an organism isolated from the bloodstream that is not related to infection as some other site (lungs, GI tract, etc.). In addition, patients must have signs of sepsis (fever, chills, hypotension, etc.):

a) Definite Catheter-related Infection

1. In association with a central line, recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture

   AND

   Catheter tip positive (>15 CFU/mL) or hub or exit site culture positive with the same organism

   OR

2. In association with a central line, a common skin contaminant\(^1\) isolated from two or more blood cultures (at least one from a venipuncture)

   AND

   Catheter tip positive (>15 CFU/mL) or hub or exit site culture positive with the same organism

b) Probable Infection

1. In association with a central line, recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture

   OR

2. In association with a central line, a common skin contaminant isolated from two or more blood cultures (at least one from a venipuncture)

c) Possible Infection

One of the following: fever (>38\(^0\)C), chills, or hypotension in association with a central line

   AND

Patients' clinical course improves with removal or change of the central line and institution of appropriate antibiotic therapy.

Comments:

___________________________________________________________________
___________________________________________________________________
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___________________________________________________________________

1 Skin contaminants include diptheroids, Bacillus species, Propionibacterium, coagulase-negative Staphylococci, or micrococci)
Category 5

**Primary blood stream infections (BSI)** must NOT be associated with a indwelling vascular device or related to infection as some other site (lungs, GI tract, etc.). In addition, patients must have signs of sepsis (fever, chills, hypotension, etc.):

a) **Definite Blood Stream Infection**

1. A recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture

   **OR**

2. A common skin contaminant\(^2\) isolated from two or more blood cultures drawn on separate occasions (from venipunctures; must not be associated with a indwelling vascular device)

   **{there is not definition of ‘probably infection’ for this category}**

c) **Possible Infection**

A common skin contaminant isolated from a blood culture that does not fulfill the definition of ‘Definite’ BSI.

   **AND**

Patients clinical course improves with institution of appropriate antibiotic therapy.

Comments:

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\(^2\) Skin contaminants include diptheroids, Bacillus species, Propionibacterium, coagulase-negative Staphylcocci, or micrococi}
Category 6

Lower urinary tract infection (LUTI)

a) Definite
Symptoms (fever (38°C), hypotension) and Pyuria (≥10 white blood cells {WBC}/ml
AND
a positive urine culture of ≥10⁵ colonies/ml urine with no more than two species of organisms
AND
No other sources of the patient’s signs and symptoms are identified

b) Probable
Symptoms (fever (38°C), hypotension)
AND
a urine culture of ≥10⁵ colonies/ml urine with no more than two species of organisms

c) Possible
a urine culture of ≥10⁵ colonies/ml urine with no more than two species of organisms

Comments:
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Category 7

**Upper Urinary Tract Infection** includes infections of the urinary tract (kidney, ureter, bladder, urethra, or tissues surrounding the retroperitoneal or perinephric spaces).

- **a) Definite:**
  Organism isolated from culture of fluid (other than urine) or tissue from affected site  
  **OR**  
  An abscess or other evidence of infection seen on direct examination, during surgery, or by histopathologic examination.

- **b) Probable**
  Two of the following: fever (>38°C), urgency, localized pain, or tenderness at involved site  
  **AND** any of the following:  
  (a) Purulent drainage from affected site  
  (b) Positive Gram stain from fluid from affected site  
  (c) Organism isolated from urine or blood culture  
  (d) Radiographic evidence of infection

- **c) Possible**
  Two of the following: fever (>38°C), localized pain, or tenderness at involved site  
  a. Physician’s diagnosis  
  b. Physician institutes appropriate antimicrobial therapy and patient responds appropriately.

Comments:

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____________________________________________________________________________________
**Category 8**

**Intra abdominal infection** includes gallbladder, bile ducts, liver [other than viral hepatitis], spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, pelvis or other intra abdominal tissue or area not specified elsewhere, and must meet the following criteria:

**a) Definite**
Organism(s) isolated from culture of purulent material from intra abdominal space/structure obtained during surgery or needle aspiration.

OR
Abscess or other evidence of intra abdominal infection (such as soilage of the peritoneal cavity after intestinal perforation) seen during surgery or by histopathologic examination.

**b) Probable**
1. In the appropriate clinical setting, **organism isolated from blood culture** and:
   Radiographic evidence for intra-abdominal infection
   OR
   clinical evidence of infection (Abdominal Pain, tenderness, jaundice)
   OR
   laboratory evidence of intra-abdominal infection (inflammatory ascitic fluid i.e > 500 PMN/ml, evidence of biliary obstruction, positive gram stain of fluid from abdominal cavity but negative cultures).

OR
2. Organisms seen on Gram stain of drainage or tissue obtained during surgery or needle aspiration but cultures are negative.

**c) Possible: one of the following:**
1. Upper Gastro-intestinal perforation or penetrating abdominal trauma that is surgically repaired without further evidence of microbiologic confirmation or clinical signs or symptoms supportive of a diagnosis of bacterial or fungal peritonitis
2. Compatible clinical illness with an inflammatory peritoneal fluid (> 500 leucocytes/ml for primary peritonitis and >100 leukocytes/ml for peritoneal dialysis related peritonitis) in the absence of a positive culture (in peritoneal fluid or blood) or gram stain
3. Organism isolated from culture of drainage from surgically placed drain (e.g., closed suction drainage system, open drain or T-tube drain).
4. Compatible clinical illness with persistent signs of systemic inflammation but without clear documented evidence of persistent inflammation within the peritoneal space following secondary bacterial peritonitis

Comments:
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Category 9

Sinusitis

a) Definite
Organism isolated from culture of purulent material directly obtained from sinus cavity by antral puncture.

b) Probable
One of the following: fever (>38°C), pain or tenderness over the involved sinus, headache, purulent exudate, or nasal obstruction

AND
Radiographic evidence of infection

c) Possible
Two of the following: fever (>38°C) or pain or tenderness over the involved sinus, headache

AND
purulent nasal exudate,

Comments:
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_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
Category 10

Lower respiratory tract infection (excluding pneumonia) includes infections such as bronchitis, tracheobronchitis, bronchiolitis, tracheitis, lung abscess, and empyema.

a) Definite:

Organism seen on smear or isolated from culture of lung tissue or fluid, including pleural fluid.

b) Probable:

1. Lung abscess or empyema seen during surgery or by histopathologic examination but no microbiological confirmation.
2. For bronchitis, tracheobronchitis, bronchiolitis, tracheitis, without evidence of pneumonia, must meet the following criterion:

   Patient has no clinical or radiographic evidence of pneumonia but has fever (>38 C) and increased sputum production

   AND

   Organism isolated from culture obtained by deep tracheal aspirate or bronchoscopy.

c) Possible

Abscess cavity seen on radiographic examination of lung.

Comments:

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______________________________  _______________________________
Category 11

ICU-Acquired Pneumonia includes HAP and VAP. It must be associated with new, progressive, or persistent infiltrates on CXR and be associated with signs and symptoms of infection (fever, leukocytosis, worsening oxygenation, purulent secretions, etc.).

a) Definite Pneumonia
  1. Radiographic evidence of pulmonary abscess and positive needle aspirate
     OR
  2. Histologic proof on open lung biopsy or at post mortem (abscess formation, or consolidation with PMN accumulation).

b) Probable Pneumonia
   Must be associated with 1 of the following:
   1. BAL (>10^4 CFU/ml) or PBC (>10^3CFU/ml) quantitative culture of specimen.
   2. Positive blood culture of an organism found within 48 hours of that same organism found in tracheal aspirate.
   3. Positive pleural fluid culture of an organism, the same organism found in tracheal aspirate.

c) Possible Pneumonia

Positive sputum or tracheal culture or non significant growth on BAL

Comments:

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Category 12

If the patient developed an infection which does not fall into any of the previous categories. Please describe below.

a) Definite  
Organism (s) or positive Gram stain isolated from a normally sterile bodily fluid or tissue in the absence of previous surgical intervention (e.g. organism isolated CSF or synovial fluid)

b) Probable  
Clinical evidence of infection and pathogenic organism(s) or positive Gram stain isolated from a body site that is not normally sterile or specimen obtained from an indwelling drain or catheter

c) Possible  
Clinical evidence of infection but no microbiologic or smear confirmation of infection

Please describe infection:
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
Appendix 8.3

Definitions of “No” Newly acquired ICU infection

If “No” to infection, choose either one, Probable No or Possible No

Probable No:
With greater certainty, the Investigator feels the patient is NOT infected. Clinical story is clearly consistent with no infection supported by lack of physiologic response (SIRS), or no positive cultures, or no treatment with antibiotics (short-term prophylaxis OK), and patient gets better.
Examples:
1) Patient with ischemic heart disease (IHD) admitted to ICU in cardiogenic shock. No positive cultures, no treatment with antibiotics, and patient gets better. Even if the patient dies, if there is no suggestion of infection or no treatment with antibiotics, the patient could still be “probably not infected”.
2) Patient with multiple traumas admitted to ICU on ventilator. Has SIRS for 24-48 hours (probably related to trauma), no organ dysfunction, no positive cultures, only short-term antibiotic prophylaxis, and gets better in a few days.
3) Clear cut cases related to “colonization” or “contamination” should be categorized here (i.e., cultures that are positive secondary to organisms likely to reflect contamination or colonization that get better with no treatment).

Possible No:
Investigator believes the patient is not infected but with some degree of uncertainty. Investigator cannot comfortably rule out infection but thinks it is not likely. Patient may manifest SIRS and organ dysfunction secondary to some other process but was treated with antibiotics.
Examples:
1) Patient admitted to ICU with severe necrotizing pancreatitis. Patient had SIRS and MODS and is treated with antibiotics from the beginning despite the lack of positive cultures. (prophylaxis for secondary pancreatic complications).
2) Patient with ischemic heart disease admitted to ICU in cardiogenic shock. CXR shows a bilateral process compatible with pulmonary edema. Patient receives treatment of IHD and cardiogenic shock and seems to improve. On Study Day 1 while in ICU, patient spikes a fever and is started on antibiotics. No positive cultures, but patient gets better.
Appendix 9
SF-36 v2 Script

SCRIPT FOR INTERVIEW ADMINISTRATION

These first questions are about your health now and your current daily activities.
Please try to answer every question as accurately as you can.

1. In general, would you say your health is . . . [READ RESPONSE CHOICES]
   (Circle one number)
   Excellent .......................................................... 1
   Very good .......................................................... 2
   Good ............................................................... 3
   Fair ..................................................................... 4
   Poor? .................................................................... 5

2. Compared to one year ago, how would you rate your health in general now? Would you say it is . . . [READ RESPONSE CHOICES]
   (Circle one number)
   Much better now than one year ago ........................................ 1
   Somewhat better now than one year ago ................................ 2
   About the same as one year ago ......................................... 3
   Somewhat worse now than one year ago ............................ 4
   Much worse now than one year ago .................................... 5

Now I'm going to read a list of activities that you might do during a typical day. As I read each item, please tell me if your health now limits you a lot, limits you a little, or does not limit you at all in these activities.

3a. First, vigorous activities, such as running, lifting heavy objects, participating in strenuous sports. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]
   [IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
   (Circle one number)
   Yes, limited a lot ..................................................... 1
   Yes, limited a little .................................................. 2
   No, not limited at all .................................................. 3
3b. moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health? (Circle one number)]

Yes, limited a lot ............................................................................................................................................1
Yes, limited a little ....................................................................................................................................2
No, not limited at all ..................................................................................................................................3

3c. lifting or carrying groceries. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health? (Circle one number)]

Yes, limited a lot ........................................................................................................................................1
Yes, limited a little ....................................................................................................................................2
No, not limited at all ..................................................................................................................................3

3d. climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health? (Circle one number)]

Yes, limited a lot ........................................................................................................................................1
Yes, limited a little ....................................................................................................................................2
No, not limited at all ..................................................................................................................................3

3e. climbing one flight of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health? (Circle one number)]

Yes, limited a lot ........................................................................................................................................1
Yes, limited a little ....................................................................................................................................2
No, not limited at all ..................................................................................................................................3
3f. ... bending, kneeling, or stooping. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)
Yes, limited a lot .................................................................................................................. 1
Yes, limited a little ..................................................................................................................... 2
No, not limited at all ................................................................................................................... 3

3g. ... walking more than a mile. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)
Yes, limited a lot .................................................................................................................. 1
Yes, limited a little ..................................................................................................................... 2
No, not limited at all ................................................................................................................... 3

3h. ... walking several hundred yards. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)
Yes, limited a lot .................................................................................................................. 1
Yes, limited a little ..................................................................................................................... 2
No, not limited at all ................................................................................................................... 3

3i. ... walking one hundred yards. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)
Yes, limited a lot .................................................................................................................. 1
Yes, limited a little ..................................................................................................................... 2
No, not limited at all ................................................................................................................... 3
3). ...bathing or dressing yourself. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)
Yes, limited a lot ................................................................. 1
Yes, limited a little .................................................................... 2
No, not limited at all ................................................................... 3

The following four questions ask you about your physical health and your daily activities.

4a. During the past four weeks, how much of the time have you had to cut down on the amount of time you spent on work or other daily activities as a result of your physical health? [READ RESPONSE CHOICES]
(Circle one number)
All of the time .......................................................................... 1
Most of the time ......................................................................... 2
Some of the time ........................................................................ 3
A little of the time ...................................................................... 4
or None of the time? .................................................................. 5

4b. During the past four weeks, how much of the time have you accomplished less than you would like as a result of your physical health? [READ RESPONSE CHOICES]
(Circle one number)
All of the time .......................................................................... 1
Most of the time ......................................................................... 2
Some of the time ........................................................................ 3
A little of the time ...................................................................... 4
or None of the time? .................................................................. 5

4c. During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health?
[READ RESPONSE CHOICES]
(Circle one number)
All of the time .......................................................................... 1
Most of the time ......................................................................... 2
Some of the time ........................................................................ 3
A little of the time ...................................................................... 4
or None of the time? .................................................................. 5
4d. During the past four weeks, how much of the time have you had difficulty performing work or other regular daily activities as a result of your physical health, for example, it took extra effort? [READ RESPONSE CHOICES]
(Circle one number)
All of the time ......................................................................................................... 1
Most of the time ........................................................................................................... 2
Some of the time ......................................................................................................... 3
A little of the time ...................................................................................................... 4
or None of the time? ................................................................................................. 5

The following three questions ask about your emotions and your daily activities.

5a. During the past four weeks, how much of the time have you had to cut down the amount of time you spent on work or regular daily activities as a result of any emotional problems, such as feeling depressed or anxious? [READ RESPONSE CHOICES]
(Circle one number)
All of the time ......................................................................................................... 1
Most of the time ........................................................................................................... 2
Some of the time ......................................................................................................... 3
A little of the time ...................................................................................................... 4
or None of the time? ................................................................................................. 5

5b. During the past four weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious? [READ RESPONSE CHOICES]
(Circle one number)
All of the time ......................................................................................................... 1
Most of the time ........................................................................................................... 2
Some of the time ......................................................................................................... 3
A little of the time ...................................................................................................... 4
or None of the time? ................................................................................................. 5
5c. During the past four weeks, how much of the time did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious? [READ RESPONSE CHOICES]

(Circle one number)

All of the time ........................................................................ 1
Most of the time .................................................................. 2
Some of the time ................................................................. 3
A little of the time ............................................................... 4
or None of the time? ............................................................ 5

6. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? Has it interfered . . . [READ RESPONSE CHOICES]

(Circle one number)

Not at all ............................................................................... 1
Slightly ............................................................................. 2
Moderately .......................................................................... 3
Quite a bit ............................................................................ 4
or Extremely? .................................................................... 5

7. How much bodily pain have you had during the past four weeks? Have you had . . . [READ RESPONSE CHOICES]

(Circle one number)

None .................................................................................. 1
Very mild ........................................................................... 2
Mild ................................................................................... 3
Moderate ............................................................................ 4
Severe ................................................................................ 5
or Very severe? .................................................................. 6

8. During the past four weeks, how much did pain interfere with your normal work, including both work outside the home and housework? Did it interfere . . . [READ RESPONSE CHOICES]

(Circle one number)

Not at all ............................................................................. 1
A little bit ............................................................................ 2
Moderately .......................................................................... 3
Quite a bit ............................................................................ 4
or Extremely? ..................................................................... 5
The next questions are about how you feel and how things have been with you during the past four weeks.

As I read each statement, please give me the one answer that comes closest to the way you have been feeling; is it all of the time, most of the time, some of the time, a little of the time, or none of the time?

9a. How much of the time during the past four weeks . . . did you feel full of life? [READ RESPONSE CHOICES]
   (Circle one number)
   All of the time.................................................................1
   Most of the time..............................................................2
   Some of the time ..............................................................3
   A little of the time............................................................4
   None of the time..............................................................5

9b. How much of the time during the past four weeks . . . have you been very nervous? [READ RESPONSE CHOICES]
   (Circle one number)
   All of the time.................................................................1
   Most of the time..............................................................2
   Some of the time ..............................................................3
   A little of the time............................................................4
   None of the time..............................................................5

9c. How much of the time during the past four weeks . . . have you felt so down in the dumps that nothing could cheer you up? [READ RESPONSE CHOICES ONLY IF NECESSARY]
   (Circle one number)
   All of the time.................................................................1
   Most of the time..............................................................2
   Some of the time ..............................................................3
   A little of the time............................................................4
   None of the time..............................................................5

9d. How much of the time during the past four weeks . . . have you felt calm and peaceful? [READ RESPONSE CHOICES ONLY IF NECESSARY]
   (Circle one number)
   All of the time.................................................................1
   Most of the time..............................................................2
   Some of the time ..............................................................3
   A little of the time............................................................4
9e. How much of the time during the past four weeks ... did you have a lot of energy? [READ RESPONSE CHOICES ONLY IF NECESSARY]
(Circle one number)
All of the time ................................................................. 1
Most of the time .............................................................. 2
Some of the time .............................................................. 3
A little of the time ............................................................ 4
None of the time .............................................................. 5

9f. How much of the time during the past four weeks ... have you felt downhearted and depressed? [READ RESPONSE CHOICES ONLY IF NECESSARY]
(Circle one number)
All of the time ................................................................. 1
Most of the time .............................................................. 2
Some of the time .............................................................. 3
A little of the time ............................................................ 4
None of the time .............................................................. 5

9g. How much of the time during the past four weeks ... did you feel worn out? [READ RESPONSE CHOICES ONLY IF NECESSARY]
(Circle one number)
All of the time ................................................................. 1
Most of the time .............................................................. 2
Some of the time .............................................................. 3
A little of the time ............................................................ 4
None of the time .............................................................. 5

9h. How much of the time during the past four weeks ... have you been happy? [READ RESPONSE CHOICES ONLY IF NECESSARY]
(Circle one number)
All of the time ................................................................. 1
Most of the time .............................................................. 2
Some of the time .............................................................. 3
A little of the time ............................................................ 4
None of the time .............................................................. 5
9i. **How much of the time during the past four weeks ... did you feel tired?** [READ RESPONSE CHOICES ONLY IF NECESSARY]
(Circle one number)

- All of the time ................................................................. 1
- Most of the time ............................................................. 2
- Some of the time ............................................................ 3
- A little of the time ........................................................... 4
- None of the time ............................................................. 5

**These next questions are about your health and health-related matters.**

Now, I'm going to read a list of statements. After each one, please tell me if it is definitely true, mostly true, mostly false, or definitely false. If you don't know, just tell me.

10. **During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives? Has it interfered ...** [READ RESPONSE CHOICES]
(Circle one number)

- All of the time ................................................................. 1
- Most of the time ............................................................. 2
- Some of the time ............................................................ 3
- A little of the time ........................................................... 4
- None of the time? ............................................................ 5

11a. **I seem to get sick a little easier than other people. Would you say that's ...** [READ RESPONSE CHOICES]
(Circle one number)

- Definitely true ............................................................... 1
- Mostly true ................................................................. 2
- Don't know ................................................................. 3
- Mostly false ............................................................... 4
- Definitely false? ........................................................... 5

11b. **I am as healthy as anybody I know. Would you say that's ...** [READ RESPONSE CHOICES]
(Circle one number)

- Definitely true ............................................................... 1
- Mostly true ................................................................. 2
- Don't know ................................................................. 3
- Mostly false ............................................................... 4
- Definitely false? ........................................................... 5
11c. I expect my health to get worse. Would you say that's... [READ RESPONSE CHOICES]
   (Circle one number)
   Definitely true .......................................................... 1
   Mostly true ............................................................ 2
   Don't know ............................................................. 3
   Mostly false ........................................................... 4
   Definitely false? ....................................................... 5

11d. My health is excellent. Would you say that's... [READ RESPONSE CHOICES]
   (Circle one number)
   Definitely true .......................................................... 1
   Mostly true ............................................................ 2
   Don't know ............................................................. 3
   Mostly false ........................................................... 4
   Definitely false? ....................................................... 5
Appendix 10
Investigator’s Confirmation

The electronic data collection was conducted under my supervision according to the protocol during the entire study.

The data and statements, including ICU acquired infection adjudication are complete and accurate to the best of my knowledge.

______________________________
Full Name of Investigator

______________________________
Signature of the Investigator

Please fax signed form to REDOXS© Project Leader at 613-548-2428 AS SOON AS POSSIBLE