

# **Antibiotics Form—Intervention**

Participant Trial Number:

**Participant Initials:** 

Randomising Site:

<u>A. Antibiotics a</u>	. Antibiotics administered — Complete this form detailing initial antibiotics administered as part of the 3 hour care bundle and continue to amend until antibiotics for initial sepsis episode are stopped. If antibiotics are restarted, complete the 'Antibiotics Form—Follow-up'								
Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	1	Frequency *	r	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/changed, indicate reason	Date and time stopped
						No/Yes	No/Yes		$\begin{array}{c} d \\ d \\ \hline m \\ \circ \\ n \\ \hline \end{array} \\ \hline y \\ h \\ h \\ \hline \end{array} \\ \begin{array}{c} m \\ m $
						Anti-in	e these us flammatory p-intestinal please sp	y and immunomodu stasis	ulatory effects
	d d = m o n = y y y y h h : m m					No/Yes	No/Yes		$\begin{array}{c} d \\ d \\ \hline m \\ o \\ n \\ \hline y \\ h \\ h \\ \hline m \\ m \\$
						Anti-in	<b>re these us</b> flammatory p-intestinal please sp	y and immunomodu stasis	ulatory effects
* complete using cod	ed lists on instructions page								
	/ (print name):				D	ate signed	J:		must be on the trial delegation log) m o n - y y y y
				Page_	of				ADAPT-Sepsis Antibiotic CRF. Version 2.0; 05-Feb-2019



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an	tibiotics for initial sepsis episode are stopp	ed. If a	ntibiot	ics are resta	rted, co	mplete the	e 'Antibioti	cs Form—Follow-u	p'
Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	Unit *	Frequency *	Route *	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/changed, indicate reason	Date and time stopped
	d d = m o n = y y y y h h m m					No/Yes	No/Yes		$\begin{array}{c} d \\ d \\ \hline m \\ o \\ n \\ \hline y \\ h \\ h \\ \hline m \\ m \\$
						Anti-in	re these us flammatory p-intestinal please spe	y and immunomodı stasis	ulatory effects
	d d <b>-</b> m o n <b>-</b> y y y y h h m m					No/Yes	No/Yes		$\begin{bmatrix} d & d & m & o & n \\ \hline m & o & n \\ \hline y & y & y & y \\ \end{bmatrix} \begin{bmatrix} h & h & m \\ \hline m $
						Anti-in Gastro	r <b>e these us</b> flammatory p-intestinal please sp	y and immunomodı stasis	ulatory effects
Form completed by	(print name):				_				must be on the trial delegation log) $m \circ n = v v v v v v$
Signature:					D	ate signed	d:	u u	ADAPT-Sepsis Antibiotic CRF. Version 2.0; 05-Feb-2019
				Page_	of				ADAR 1-SEPSIS AIILIDIOLIC CRF. VEISIOII 2.0, 05-FED-2019



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Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	Unit *	Frequency *	Route *	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/changed, indicate reason	Date and time stopped
	d d = m o n = y y y y h h m m					No/Yes	No/Yes		$\begin{array}{c} d \\ d \\ \hline m \\ o \\ n \\ \hline y \\ h \\ h \\ \hline m \\ m \\$
						Anti-in	re these us flammatory p-intestinal please spe	y and immunomodı stasis	ulatory effects
	d d <b>-</b> m o n <b>-</b> y y y y h h m m					No/Yes	No/Yes		$\begin{bmatrix} d & d & m & o & n \\ \hline m & o & n \\ \hline y & y & y & y \\ \end{bmatrix} \begin{bmatrix} h & h & m \\ \hline m $
						Anti-in Gastro	r <b>e these us</b> flammatory p-intestinal please sp	y and immunomodı stasis	ulatory effects
Form completed by	(print name):				_				must be on the trial delegation log) $m \circ n = v v v v v v$
Signature:					D	ate signed	d:	u u	ADAPT-Sepsis Antibiotic CRF. Version 2.0; 05-Feb-2019
				Page_	of				ADAR 1-SEPSIS AIILIDIOLIC CRF. VEISIOII 2.0, 05-FED-2019

#### Completion Guidelines for CRF 5: Antibiotics Form—Intervention

This is a rolling CRF to be updated as antibiotics prescribed change during a patient's care, therefore ensure this is signed off as each page is completed or at the end of the intervention period, whichever is first.

Participant Initials:	Write the initials of the participant's first/given name and surname/family name only. For double barrelled surnames/ family names use the initial from the first part of the surname/family name.
Dates:	Please use the following formats for dates: 06-Jun-1956.
Times:	Please record all times in the 24-hour format.

Page\_\_\_\_ of \_\_\_\_\_

### Completion Guidelines for CRF 5: Antibiotics Form—Intervention

• When completing the table please enter the numerical code corresponding to the following antibiotics as applicable:

Code	Antibiotic	Code	Antibiotic
1	AMIKACIN	32	DEMECLOCYCLINE HYDROCHLORIDE
2	AMOXICILLIN	33	DOXYCYCLINE
3	AMPICILLIN	34	ERTAPENEM
4	AMPICILLIN WITH FLUCLOXACILLIN	35	ERYTHROMYCIN
5	AZITHROMYCIN	36	FIDAXOMICIN
6	AZTREONAM	37	FLUCLOXACILLIN
7	BENZYLPENICILLIN SODIUM (Penicillin G)	38	FOSFOMYCIN
8	CEFACLOR	39	GENTAMICIN
9	CEFADROXIL	40	IMIPENEM WITH CILASTATIN
10	CEFALEXIN	41	LEVOFLOXACIN
11	CEFIXIME	42	LINEZOLID
12	CEFOTAXIME	43	LYMECYCLINE
13	CEFRADINE	44	MEROPENEM
14	CEFTAROLINE FOSAMIL	45	METHENAMINE HIPPURATE (Hexamine hippurate)
15	CEFTAZIDIME	46	METRONIDAZOLE
16	CEFTAZIDIME WITH AVIBACTAM	47	MINOCYCLINE
17	CEFTOBIPROLE	48	MOXIFLOXACIN
18	CEFTOLOZANE WITH TAZOBACTAM	49	NALIDIXIC ACID
19	CEFTRIAXONE	50	NEOMYCIN SULFATE
20	CEFUROXIME	51	NITROFURANTOIN
21	CHLORAMPHENICOL	52	NORFLOXACIN
22	CIPROFLOXACIN	53	OFLOXACIN
23	CLARITHROMYCIN	54	OXYTETRACYCLINE
24	CLINDAMYCIN	55	PHENOXYMETHYLPENICILLIN (Penicillin V)
25	CO-AMOXICLAV	56	PIPERACILLIN WITH TAZOBACTAM
26	CO-FLUAMPICIL	57	PIVMECILLINAM HYDROCHLORIDE
27	COLISTIMETHATE SODIUM	58	RIFAMPICIN
28	CO-TRIMOXAZOLE		RIFAXIMIN
29	DALBAVANCIN	60	SODIUM FUSIDATE (Fusidic acid)
30	DAPSONE		STREPTOMYCIN
31	DAPTOMYCIN	62	SULFADIAZINE

Code	Antibiotic
63	TEDIZOLID
64	TEICOPLANIN
65	TELAVANCIN
66	TEMOCILLIN
67	TETRACYCLINE
68	TICARCILLIN WITH CLAVULANIC ACID
69	TIGECYCLINE
70	TINIDAZOLE
71	TOBRAMYCIN
72	TRIMETHOPRIM
73	VANCOMYCIN
74	OTHER

#### Completion Guidelines for CRF 5: Antibiotics Form—Intervention

• When completing section A, please enter the numerical codes corresponding to the following units, frequency, routes and reasons as applicable:

Code	Unit
1	g
2	mg
3	other

			-		
Code		Frequency		Code	Route
	1	Once daily—Od		1	
	2	Twice daily—Bd		1	IV .
		,		2	Oral
		Three times daily—Tds		3	Rectal
	4	Four times daily—Qds			Nebuliser
	5	One off		4	Nebulisei
	6	Continuous infusion			

Code	Reason for change
1	Antibiotic escalation
2	Antibiotic de-escalation
3	Re-infection/recurrence
4	New infection/superinfection
5	Clinical relevant suspected antibiotic associated adverse reaction (complete Antibiotic Adverse reaction CRF)
6	Antibiotics stopped
7	Other, please specify

- For antibiotics given at regular intervals (e.g. antibiotic X three times a day), record the value of an individual dose and then complete relevant frequency.
- For antibiotics given as continuous infusions, record the total dose given over the last 24 hours based on the patient prescription and the recorded units and complete the frequency column with code 7 for continuous infusion.

Page\_\_\_\_ of \_\_\_\_

#### Completion Guidelines for CRF 5: Antibiotics Form—Intervention

#### Guidance on Macrolide drugs: Erythromycin, Azithromycin and Clarithromycin

These drugs can sometimes be used for their effects other than for treating infection.

 Used long term (many months) for their anti-inflammatory and immunomodulatory effects in patients with chronic lung diseases (e.g. COPD, bronchiectasis and asthma). It is likely that if a patient is admitted to critical care with sepsis, these drugs will not be continued for this purpose. However, they may be reintroduced later (perhaps within 28-days) or commenced as new therapy in a patient with chronic lung disease. If these drugs are given in this way, they need to be indicated as such in the antibiotic forms (intervention and follow up).

2. Erythromycin is sometimes used in an attempt to treat gastro-intestinal stasis in critical illness. It is an unlicensed use for this purpose and we do not recommend its use in this way. However, if it is used for this purpose and not for the treatment of infection, this will need indicating on the antibiotic forms (intervention and follow-up)

For any use of a macrolide antibiotic in ADAPT-Sepsis, it is important that the research team discuss with the clinical team why they are being given within the intervention and follow up periods.