15. Explanation for Program Changes or Adjustments

There are 2 forms being deleted as a part of this revision and 1 new form being added. Most of the collection activities remain the same, however, there are a few proposed revisions including minor revised language and re-wording to improve clarity and readability of the data collection forms.

Details of each collection instrument for the revision are as follows:

ABCs:

This Revision includes proposed changes to 3 of the 5 approved Active Bacterial Core surveillance (ABCs) forms and no new ABCs data collection tools (form/s) detailed below:

Changes to Approved Forms:

- ABC.100.1 ABCs Case Report Form
- ABC.100.3 ABCs H. *influenzae* Neonatal Sepsis Expanded Surveillance Form
- ABC.100.4 ABCs Severe GAS Infection Supplemental Form Form

Approved Forms with **no changes** noted:

- ABC.100.2 ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form
- ABC.100.5 ABCs Neonatal Infection Expanded Tracking Form
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ABCs Case Report Form (ABC.100.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Update burden estimate and no change to form	Updated burden estimate to account for increased number of cases observed in the last couple of years.	Increased by 581 hours
ABCs H. *influenzae* Neonatal Sepsis Expanded Surveillance Form (ABC.100.3)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Remove form and update burden estimate	Removing form since data is no longer being collected. This form is being discontinued because the surveillance activity for which it was developed has ended. Consequently, there is no longer a programmatic or operational need to collect information using this instrument.	Decreased by 10 hours

ABCs Severe GAS Infection Supplemental Form (ABC.100.4)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Remove form and update burden estimate	Removing form since data is no longer being collected. This form is being discontinued because the associated surveillance activity is no longer mandatory for participating sites. As participation is now optional, continued data collection using this form is not necessary to support required surveillance objectives, resulting in a reduction of respondent burden.	Decreased by 453 hours

HAIC:

This Revision includes proposed changes to 2 of 13 approved Healthcare-Associated Infections – Community Interface (HAIC) data collection tools (form/s) detailed below and an addition of 1 new collection form.

Changes to Approved Forms:

- HAIC.400.4 Invasive Staphylococcus aureus Infection Case Report Form
- HAIC.400.5 Invasive Staphylococcus aureus Laboratory Survey

Addition of New Form:

- HAIC.400.14 HAIC MuGSI KPC and NDM treatment collection form

Approved Forms with **no changes** noted:

- HAIC.400.1 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form
- HAIC.400.2 MuGSI CA CP-CRE Health interview
- HAIC.400.3 MuGSI Supplemental Surveillance Officer Survey
- HAIC.400.6 Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey
- HAIC.400.7 CDI Case Report and Treatment Form
- HAIC.400.8 Annual Survey of Laboratory Testing Practices for C. difficile Infections
- HAIC.400.9 CDI Annual Surveillance Officers Survey
- HAIC.400.10 C. difficile Surveillance Nursing Home Telephone Survey (LTCF)
- HAIC.400.11 Candidemia Case Report Form
- HAIC.400.12 Laboratory Testing Practices for Candidemia Questionnaire
- HAIC.400.13 Death Ascertainment Project

HAIC.400.4 Invasive Staphylococcus aureus Infection Case Report Form		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Addition	10a. WHAT TYPE OF HEALTH INSURANCE DID THE PATIENT HAVE AT THE TIME OF THE DISC? (Check all that apply) • Medicaid • Medicare • Private Insurance (including TRICARE) • VA Care • Self-pay (includes uninsured) • No charge • Other (specify):_____ • Unknown **Justification:** Type of health insurance has been associated with certain outcomes relevant to *S. aureus* infection, including appropriate treatment on discharge, which could impact disease recurrence and survival. The addition of this question will allow for description of how insurance type might or might not be associated with specific invasive *S. aureus* outcomes of interest in this surveillance population.	1 minute increase
Revision – replaced free text field with discrete selections/checkboxes	28a. DOES THE PATIENT HAVE: IMPLANTED CARDIAC DEVICE (E.G., PROSTHETIC HEART VALVE, PACEMAKER, AICD, LVAD)? •Yes • No • Unknown IF YES, is it associated with the MRSA/MSSA infection? • Yes • No • Unknown If associated with the infection, specify type (check all that apply): • CIED pocket/generator infection • CIED lead infection • CIED unspecified infection location	No change

	• Prosthetic heart valve • LVAD driveline infection • LVAD pump/pump pocket infection • LVAD unspecified infection location • Other, specify:_____ IMPLANTED ORTHOPEDIC DEVICE (E.G., PROSTHETIC JOINT OR ORTHOPEDIC HARDWARE)? • Yes • No • Unknown IF YES, is it associated with the MRSA/MSSA infection? • Yes • No • Unknown If associated with the infection, specify type (check all that apply): • Prosthetic joint, hip • Prosthetic joint, knee • Prosthetic joint, other • Hardware, spine • Hardware, other • Other, specify: **Justification:** The phrase, "If associated with the infection, specify type" replaces the previous "Yes, specify" text field and adds discrete checkbox selections that represent the most common responses that were written in to the previous free text field. This will improve efficiency by eliminating typed free text and providing standardized categories that fit most circumstances. A free text "Other, specify" field remains for uncommon situations not represented by the checkboxes.	
Revision – replaced free text field with discrete selections/checkboxes	28b. DOES THE PATIENT HAVE ANOTHER TYPE OF IMPLANTED PROSTHETIC DEVICE ASSOCIATED WITH THE INFECTION? • Yes • No • Unknown IF YES, specify type (check all that apply):	No change

	• CSF shunt/drain • Percutaneous drain/tube (non-CSF) • Urinary catheter or stent • Other, specify:_____ **Justification:** The revision adds discrete checkbox selections that represent the most common responses that were written in to the previous "Yes, specify" text field. This will improve efficiency by eliminating typed free text and providing standardized categories that fit most circumstances. A free text "Other, specify" field remains for uncommon situations not represented by the checkboxes.	
Revision – replaced many discrete questions with succinct summary questions	31. INJECTION DRUG USE (IDU): • Yes • None documented • Unknown If IDU, which substance(s) (check all that apply) • Opioid, schedule I • Opioid, schedule II-IV • Opioid, NOS • Cocaine • Methamphetamine • Other (specify): • Unknown substance If IDU, did the patient receive medication assisted treatment (MAT)/ medication for opioid use disorder (MOUD) during the current hospitalization? • Yes • No • NA (not hospitalized or does not inject opioids) **Justification:** Injection drug use is associated with increased risk of invasive *S. aureus* infection, including bacteremia and endocarditis. This revision retains this important information relevant to injection drug use and eliminates questions about non-injection substance use. This substantially streamlines the data collection and will improve efficiency for substance use data collection.	1 minute decrease

HAIC.400.5 HAIC-Invasive Staphylococcus aureus Laboratory Survey		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Added explanatory language	Thank you for completing this survey. We are asking you to complete this survey because your laboratory serves the catchment area for the Emerging Infections Program's (EIP) culture-based invasive *S. aureus*/MRSA surveillance program. Our aim for this survey is to understand how *S. aureus*/MRSA are identified from normally sterile site specimens in your lab. We also aim to understand circumstances in which identification of *S. aureus*/MRSA in a normally sterile site specimen may not be reported to EIP staff, potentially resulting in a missed surveillance case (e.g., if only positive cultures/isolates are reported in the line list, and a culture-independent diagnostic test is used). ***PLEASE NOTE THAT ALL OF THE QUESTIONS APPLY TO TESTING OF SPECIMENS FROM NORMALLY STERILE SITES*** (e.g., blood, CSF, bone, peritoneal fluid, etc.). (Do NOT include testing procedures for non-sterile site colonization, such as nasal or rectal swabs.) Change: Added language to improve the flow of the survey. Justification: This language adds clarity and context to the individual completing the survey.	No impact to burden.
Wording change	Prior Question: 2. During the past year (i.e., in the past 12 months or since the completion of the last lab survey), has your lab changed testing methods used to detect any of the following pathogens: Updated Question: 2. During the past year (i.e., in the past 12 months or since the completion of the last lab survey), has your lab changed testing methods used to detect MRSA or *S. aureus* from normally sterile site (e.g., blood, CSF, bone) specimens? Change: Add the language "MRSA or S. aureus from normally sterile sites (e.g., blood, CSF, bone) specimens?" Justification: This language adds clarity to the question to improve data quality.	No impact to burden
Wording change	4. If a sterile site culture is positive, is sub-culturing to obtain an isolate always performed?? Yes GO TO Q4b, No Updated question: 4. If a culture is positive, is an isolate always obtained?	No impact to burden

	Yes GO TO Q4b, No GO TO Q4a Change: Deleted words “sterile site” and specific mention of subculturing Justification: This language adds clarity to the question to improve data quality.	
New Question	4b. Are any tests used to identify *S. aureus* performed offsite? □ No, **all** *S. aureus* identification performed On-site – GO TO Q4c □ Yes, **some** *S. aureus* identification performed offsite please specify offsite lab and tests (if known) _____ – GO TO Q4c □ Yes, **all** *S. aureus* identification performed offsite please specify offsite lab and tests (if known) _____ - GO TO Q5 Change: New question Justification: By adding this question, the survey is being streamlined based on the labs practices.	The burden of the question is expected to be 30 second.
Replacement question	4c. If a culture is positive, how do you identify it as *S. aureus*? (Check all that apply) ☐ MALDI-TOF ☐ Biochemical tests, manual or automated (e.g., catalase, coagulase, Microscan, Vitek, Pheonix) ☐ Other non-molecular test (e.g., latex agglutination, selective media), specify: _____ ☐ Molecular test other than MALDI-TOF (e.g., NAAT, PCR) – If you use molecular tests, GO TO 4d; if you do not use molecular tests GO TO Q4e Change: This question is replacing the following question: 4b. If a sterile site culture is positive, how do you identify it as *S. aureus*? This includes identifying both on-site (in-house) or at another lab. (Check all that apply) □ MALDI-TOF – GO TO 4f	No change to burden.

	◻ Biochemical tests (e.g., catalase, coagulase) – GO TO 4f ◻ Molecular test – GO TO 4c ◻ Other, specify: _____ – GO TO 4f ◻ Do not identify as *S. aureus*– GO TO Q5 Justification: Language in this question was clarified to improve data quality.	
Removed question	If molecular test(s) used] Where is molecular testing from a positive sterile site culture completed? ◻ On-site ◻ Send out, please specify lab _____ - GO TO Q4e Change: This question from the prior version of this survey was removed. Justification: The revision to question 4c streamlined the collection of this data and this question is no longer needed.	Reduced burden to the form by 30 second.
Wording Change and removal of date fields in associated sub-questions	4d. Which molecular tests are used? Please check all that apply. Change: The wording of this question was changed from: Which molecular tests do you use (cultures from sterile site sources only, i.e. blood, CSF, pleural fluid, bone, etc.)? Please check all that apply. Removed all fields for "date started" next to "check all that apply" options. Justification: The revision to question 4b and 4c streamlined the collection of this data and this question in turn needed to have the language changed. Date fields were determined to be no longer needed for this question.	No change to burden.
Removed Question and associated sub-questions	[If not using molecular tests from sterile site cultures on-site] Do you plan to start offering any molecular tests for detection of *S. aureus* or MRSA from a positive sterile source culture within the next year? ◻ Yes ◻ No – GO TO Q5 When do you plan to start offering molecular tests? Month/Year: ____/____ Where do you plan to have molecular tests performed? ◻ On-site ◻ Send out, please specify lab _____ - GO TO Q5	Reduced burden to the form by 30 second.

	Change: this question was removed. Justification: with the change in testing practices this question is no longer needed.	
New Question and associated sub-questions	4e. Do you anticipate any changes to testing/identification processes for *S. aureus* or MRSA from a positive sterile source culture within the next year? □ Yes – GO TO Q4f □ No – GO TO Q5 4f. Specify testing changes: _____ 4g. When do you plan to make this change? Month/Year: ____/____ Change: This is a new question. Justification: This question was revised from the previous 4e, which was removed. This allows for more flexibility in responses about changes in testing practices.	The burden of the question is expected to be 30 second.
Wording change and number change	5a. [If yes] Which tests are used to detect *S. aureus* directly from a normally sterile site specimen without culture? (sterile site sources only, i.e. blood, CSF, pleural fluid, bone, etc.)? Please check all that apply. Change: This was previously question 5b, also added "if yes" . Justification: This change will improve the flow of the survey.	No change to burden
Number change and skip pattern change	5b. [If yes] Where is this testing completed? □ On-site □ Send out, please specify lab _____ - Change: this question changed from 5a to 5b. Removed skip pattern. Justification: moving this question improved the flow of the survey.	No change to burden.
Wording change and number change	5d. Do positive culture-independent diagnostic tests directly from normally sterile specimens appear in the *S. aureus* surveillance laboratory line lists (even if no positive associated culture)? □ Yes □ No Change: This question was previously number 5c and read as follows: 5c. Are all positive tests directly from sterile sources appearing in the *S.*	No change in burden.

	aureus surveillance laboratory line lists? ◻ Yes ◻ No Justification: The moving of this question and change of the language will improve the flow of the survey and the quality of the data collection.	
Wording change and number change	5f. If yes, which tests do you plan to use to detect *S. aureus* directly from a sterile site source without culture? (sterile site sources only, i.e. blood, CSF, pleural fluid, bone, etc.)? Please check all that apply. Change: This was previously question 5h, also added "if yes" . Justification: This change will improve the flow of the survey.	No change to burden.
Number change	5g. When do you plan to start offering these tests? Month/Year: ____/____ Change: This was previously 5f Justification: This change will improve the flow of the survey.	No change to burden
Number change	5h. Where do you plan to have these tests performed? ☐ On-site ☐ Send out, please specify lab _____ Change: This was previously 5g Justification: This change will improve the flow of the survey.	No change to burden

HAIC.400.14 HAIC MuGSI KPC and NDM treatment collection form (New Form)

Type of Change	Itemized Changes / Justification	Impact to Burden
New Question	2a. Administered to treat CRE For each of the following antibiotics answer: yes, no, unknown. Amikacin Aztreonam Aztreoman avibactam Cefepime Cifiderocol Ceftriaxone	This question is expected to take about 9 minutes to complete.

	Cefotaxime Ceftazidime Ceftazidime-avibactam Ceftolozane-tazobactam Ciprofloxacin Colistin or Polymyxin E Cefepime-enmetazobactam Doripenem Doxycycline Eravacycline Ertapenem Fosfomycin Gentamicin Imipenem Imipenem-relebactam Levofloxacin Meropenem Meropenem-vaborbactam Minocycline Nitrofurantoin Moxifloxacin Piperacillin-Taxobactam Plazomicin Polymixin B Tigercycline Trimethoprim-sulfamethoxazole Tobramycin Other (please specify) Changes: Adding this as a new question to a new data collection form. Justification: This purpose of this data collection tool is to understand what antibiotics are being used to treat CRE. This question aides in understanding what drugs were used for treatment.	
New Question	3a. Start Date; 3b. Stop Date; 3c. Start Date, 3d, Stop Date; 3e. Start Date, 3f. Stop Date; 3f. Treatment continued after hospital discharge: answer Yes, No, Unknown The above questions will be asked for each of the antibiotics below. Amikacin Aztreonam Aztreoman avibactam	This question is expected to take about 10 minutes to complete.

	Cefepime Cifiderocol Ceftriaxone Cefotaxime Ceftazidime Ceftazidime-avibactam Ceftolozane-tazobactam Ciprofloxacin Colistin or Polymyxin E Cefepime-enmetazobactam Doripenem Doxycycline Eravacycline Ertapenem Fosfomycin Gentamicin Imipenem Imipenem-relebactam Levofloxacin Meropenem Meropenem-vaborbactam Minocycline Nitrofurantoin Moxifloxacin Piperacillin-Taxobactam Plazomicin Polymixin B Tigercycline Trimethoprim-sulfamethoxazole Tobramycin Other (please specify) – this could be answered up to X times. Changes: Adding this as a new question to a new data collection form. Justification: This purpose of this data collection tool is to understand what antibiotics are being used to treat CRE. Having start and stop dates for each treatment antibiotic is important in understand duration of treatment.	
New Question	4a. Was ID consulted for the treatment of the CRE infection? Yes, No, Unknown Changes: Adding this as a new question to a new data collection form. Justification: The purpose of this data collection tool is to understand treatment that a patient receives. Understanding if a patient with a positive culture for CRE had an infection disease (ID) consultation for that treatment	This question is expected to take 1 minute to complete.

	is important.	
New Question	4b. If yes, report the date of initial ID consult (or reconsult): Date. Changes: Adding this as a new question to a new data collection form. Justification: The purpose of this data collection tool is to understand treatment that a patient receives. Understanding when the patient with a positive culture for CRE had an infection disease (ID) consultation is important in understanding the patients disease course.	This question is expected to take 1 minute to complete.
New Question	4c. Were there any antibiotics noted by a clinician that could not be used for CRE treatment because they were not available or not on formulary? Yes, No, Unknown. 4d. If yes, please specify the antibiotics: Changes: Adding this as a new question to a new data collection form. Justification: The purpose of this data collection tool is to understand what antibiotics could not be used for CRE treatment because they were not available or not on formulary. This question aides in understanding what drugs were not available to the patient for treatment.	This question is expected to take 5 minutes to complete.
New Question	5a. Was the incident specimen tested for carbapenemase genes: yes, no, unknown Change: Adding this as a new question to a new data collection form. Justification: KPC and NDM are types of carbapenemases. Understanding whether at the time of treatment, the treating provider knew that the patient was positive for a carbapenemase, is important, particularly since treatment may vary by carbapenemase type.	This question is expected to take 1 minute to complete.
New Question	5b. If yes, what testing method was used (check all that apply)? Automated Molecular Assay □ Carba-R □ Check Points □ Immunochromatographic lateral flow tests (ICT) □ MALDI-TOF MS □ Next Generation NucleicAcid Sequencing □ PCR □ Streck ARM-D □ Other (specify):_____ □ Unknown	This question is expected to take 1 minute to complete.

	Change: Adding this as a new question to a new data collection form. Justification: The accuracy of the type of testing method for carbapenemase tests can vary, therefore this is important to understand how accurate the carbapenemase testing results were when the patient was treated.	
New Question	5c. If yes, dates of testing. Change: Adding this as a new question to a new data collection form. Justification: Understanding the temporality between the date of positive carbapenemase test and the dates of the antibiotic prescribed are helpful in better understanding the patient's treatment course.	This question is expected to take 1 minute.
New Question	5d. If tested, what was the testing results? NDM: Pos, Neg, Ind, Unk KPC: Pos, Neg, Ind, Unk Change: Adding this as a new question to a new data collection form. Justification: Understanding whether the treating physician knew the tspecific carbapenemase (KPC or NDM) that the patient was positive for, is important to understanding the complete picture of the patient's treatment course, as the course may change based on the type of carbapenemase.	This question is expected to take 1 minute to complete.
New Question	6a. Highest body temperature (F or C) on the day of DISC Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6b. Lowest body temperature (F or C) on the date of DISC Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6c. Has the patient had an acute hypotensive event with drop in systolic blood pressure >30 mm Hg and diastolic blood pressure >20 mm Hg on the date of the DISC: Yes, No, Unknown	This question is expected to take 1 minute to complete.

	Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	
New Question	6d. Systolic blood pressure (lowest value) on the day of the DISC. Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6e. Is the patient receiving mechanical ventilation on the day of the DISC? Yes, No, Unknown	This question is expected to take 1 minute to complete.
New Question	6f. Patient has a respiratory rate of > 25 breaths per minute on the date of DISC: Yes, No, Unknown Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6g. Has the patient had a cardiac arrest on the date of DISC or within 48 hours before the DISC? Yes, No, Unknown Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6h. Is the patient receiving intravenous vasopressors (medications to help raise blood pressure) on the date of the DISC? Yes, No, Unknown Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	This question is expected to take 1 minute to complete.
New Question	6i. Mental state on the date of DISC (check all that apply)	This question is expected to take 2

	□ Alert (normal) □ Disoriented □ Stuporous □ Comatose □ Sedated □ Unknown Change: Adding this as a new question to a new data collection form. Justification: The calculation of the Pitt Bacteremia Score will support in understanding the severity of the patient's disease. This is one of the questions that enable the calculation of that score.	minutes to complete.
New Question	7a. Susceptibility results (AST) from the medical record. For each of the antimicrobials listed below, the MIC or zone diameter (clinical lab), Interpretations (clinical lab), AST result Date (clinical lab), Interpretation (SPHL/ARLN), and AST result date (SPHL/ARLN) will be collected Amikacin Aztreonam Aztreoman avibactam Cefepime Cefiderocol Ceftriaxone Cefotaxime Ceftazidime Ceftazidime-avibactam Ceftolozane-tazobactam Ciprofloxacin Colistin or Polymyxin E Cefepime-enmetazobactam Doripenem Doxycycline Eravacycline Ertapenem Fosfomycin Gentamicin Imipenem Imipenem-relebactam Levofloxacin Meropenem Meropenem-vaborbactam Minocycline Nitrofurantoin Moxifloxacin Piperacillin-Taxobactam	This question is expected to take 10 minutes to complete.

	Plazomicin Polymixin B Tigercycline Trimethoprim-sulfamethoxazole Tobramycin Other (please specify) Change: Adding this as a new question to a new data collection form. Justification: Understanding the testing antimicrobial testing results of the patient's isolate is important in understanding if the antimicrobial that the patient was treated with was appropriate. This is a key component in understanding treatment.	
New Question	7b. Susceptibility results from the ET, KB, MD, PX, SEN, VK, APS data sources in lab reports For each of the antimicrobials listed below, the MIC or zone diameter (clinical lab), Interpretations (clinical lab), AST result Date (clinical lab), Interpretation (SPHL/AR Lab Network), and AST result date (SPHL/AR Lab Network) will be collected Amikacin Aztreonam Aztreonam-avibactam Cefepime Cefiderocol Ceftriaxone Cefotaxime Ceftazidime Ceftazidime-avibactam Ceftolozane-tazobactam Ciprofloxacin Colistin or Polymyxin E Cefepime-enmetazobactam Doripenem Doxycycline Eravacycline Ertapenem Fosfomycin Gentamicin Imipenem Imipenem-relebactam Levofloxacin Meropenem Meropenem-vaborbactam	This question is expected to take 10 minutes to complete.

	Minocycline Nitrofurantoin Moxifloxacin Piperacillin-Taxobactam Plazomicin Polymixin B Tigercycline Trimethoprim-sulfamethoxazole Tobramycin Other (please specify) Change: Adding this as a new question to a new data collection form. Justification: Understanding the testing antimicrobial testing results of the patient's isolate is important in understanding if the antimicrobial that the patient was treated with was appropriate. This is a key component in understanding treatment.	