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| **Appendix 1. Definitions of severe mastitis, mastitis or breast inflammation and breastfeeding cessation** | |
| **Severe Mastitis** | |
| Women were categorized as having severe mastitis if they had any of the following signs or symptoms documented during a study visit: | |
| A diagnosis of mastitis from an adverse event report; OR | |
| An affirmative answer to one of the following questions for either breast, after a clinical evaluation and palpation of the mother’s breast during a breast exam: | |
| BE9 | Are breasts discolored or shiny? |
| BE14 | Does breast feel hard? |
| BE15 | Does breast feel lumpy? |
| BE16 | Are lumps tender? |
| BE17 | Does breast feel hot? |
| BE18 | Does exam cause pain? |
| BE19 | Are axilla nodes tender? |
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| **Mastitis or Breast Inflammation** | |
| Women were categorized as having mastitis or breast inflammation if they had any of the following signs or symptoms documented during a study visit: | |
| Had severe mastitis as described above; OR | |
| An affirmative answer to one of the following questions for either breast, after a clinical evaluation and palpation of the mother’s breast during a breast exam: | |
| BE4 | Are there any cracks on tip of nipple? |
| BE5 | Is there any bleeding/dried blood on nipple? |
| BE6 | Is there nipple rash? |
| BE7 | Is there nipple exudate? |
| BE10 | Are there any open or oozing sores on breast? |
| BE11 | Are there any open or oozing sores on areola and adjacent area? |
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| **Breastfeeding Cessation** | |
| Breastfeeding cessation was indicated if women provided the answer that follows to each of these questions | |
| IFQ1 | “Did you breastfeed the baby since last visit?” (No) |
| IFQ38 | Since the last visit, have you tried to stop breastfeeding your baby?”  (No, stopped before last visit) |
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| And women consistently indicated that they were not breastfeeding by providing the indicated answer to any of the following questions: | |
| IFQ1 | Did you breastfeed the baby since last visit?” (No) |
| IFQ4 | Does your baby breastfeed at night?” (No) |
| IFQ7 | Since the last visit, did your *baby* receive anything to drink or eat other than breast milk?” (No) |
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| \* Severe mastitis, mastitis or breast inflammation and breastfeeding cessation were defined using data from adverse event reports, breast exams and infant feeding questionnaires | |