

CORRECTED COPY

November 20, 2002

CHDP Provider Information Notice No.: 02-09

TO: ALL COUNTY CHILD HEALTH AND DISABILITY PREVENTION
(CHDP) PROGRAM DIRECTORS, DEPUTY DIRECTORS, MEDICAL
CONSULTANTS, STATE CHILDREN'S MEDICAL SERVICES (CMS)
BRANCH STAFF AND REGIONAL OFFICE STAFF

SUBJECT: CHDP HEALTH ASSESSMENT GUIDELINES REVISIONS AND
UPDATES

This purpose of this information notice is to advise you of the changes to the CHDP
Health Assessment Guidelines:

- Expanded policy concerning Clinical Laboratory Improvement Amendments (CLIA) of 1988 waived test systems for use in hemoglobin, hematocrit and urinalysis testing;
- Revised recommendations from the Centers for Disease Control and Prevention (CDC) for diagnosis and treatment of iron deficiency anemia, and
- Revised and updated CHDP Health Assessment Guidelines for Sections 701, 702, Table 701.1 and Appendix R.

CLIA Waived Test Systems

CLIA established standards for improving the quality of clinical laboratory testing in the United States. One intent of these standards was the regulation of smaller, provider-based laboratories, such as those operated by health-care providers participating in the CHDP Program. CLIA regulations are based on the complexity of the test method and include waived and non-waived test systems. A Waived test system is one that is simple and highly accurate, with an insignificant risk of erroneous results. Accurate, low-cost clinic-based instruments, that are FDA approved and CLIA



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Children's Medical Services Branch
714/744 P Street, P.O. Box 942732, Sacramento, CA 94234-7320
(916) 327-1400

Internet Address: <http://www.dhs.ca.gov/pcf/cms>

waived have been developed for measuring hemoglobin and hematocrit concentration by using capillary or venous blood, and for testing urine for urinalysis.

This information notice is to inform you that CHDP Program providers may use any of the FDA approved CLIA waived test systems for the determination of hemoglobin, hematocrit, or urinalysis in the office/clinic. The most current listing of waived test systems for hematology and urinalysis can be found at <http://www.cap.org/html/lip/waived.html>. Please note that the CHDP Program does not specifically endorse any test system or manufacturer. The CHDP Health Assessment Guidelines, Section 701 and 702 have been revised to state that any FDA approved CLIA waived test system is acceptable for hemoglobin, hematocrit, or urinalysis testing.

When providers use CLIA waived tests they are required to comply with CLIA mandated quality assurance practices for hemoglobin screening in their clinical laboratories according to the manufacturer's instructions. Providers should also ensure that individuals who draw blood and process hemoglobin or hematocrit tests also meet CLIA and California requirements and are appropriately trained and rechecked on procedures (e.g., appropriate finger stick techniques).

For those providers with laboratories using nonwaived test systems (e.g., BMS Hemoglobinometer™, American Optical Hb-Meter™, an automated hematology analyzer), this is a reminder that these laboratories are required to comply with a series of quality standards, including participation in a proficiency testing program. These laboratories must obtain and maintain a CLIA certificate of registration or accreditation.

Diagnosis and Treatment of Anemia

To ensure that the most up to date information is available to you we have revised the Health Assessment Guidelines for the diagnosis and treatment of anemia. In summary, the following are recommendations from the U.S Department of Health and Human Services, 1998 report: "Recommendations to prevent and control iron deficiency in the United States":

- Check a positive anemia screening result by performing a repeat hemoglobin concentration or hematocrit test.
- Treat presumptive iron-deficiency anemia by prescribing 3mg/kg per day of iron drops to be administered between meals.
- Repeat the anemia screening in four weeks. An increase in hemoglobin concentration of greater than or equal to 1g/dL or in hematocrit of greater than or equal to 3 percent confirms the diagnosis of iron-deficiency anemia. Continue iron treatment for two more months, reinforce dietary counseling, and then recheck

hemoglobin concentration or hematocrit. Reassess hemoglobin concentration or hematocrit approximately six months after successful treatment is completed.

- If after the initial four weeks the anemia does not respond to iron treatment and there has been compliance with the iron supplementation regimen and an absence of acute illness, further evaluate the anemia by using other laboratory tests, including mean cell volume (MCV), red blood cell distribution width (RDW), and serum ferritin concentration.

Revisions and Updates in the CHDP Health Assessment Guidelines

The CHDP Health Assessment Guidelines, Section 701, table 701.1 and appendix R have been revised, updated, and changes in current policy have been made to reflect the latest recommendations from the CDC. Table 701.1 has been modified to update the current hemoglobin and hematocrit levels. Appendix R has been modified to update the current recommendations for diagnosis and treatment of anemia.

You will find the revised Sections 701, 702; table 701.1 and appendix R enclosed. Please ensure that these revisions are inserted into your CHDP Health Assessment Guidelines.

If you have any questions, please contact your local CHDP Program.

Original Signed by Harvey Fry for Maridee Gregory, M.D.

Maridee A. Gregory, M.D., Chief
Children's Medical Services Branch

Enclosures

HEMOGLOBIN OR HEMATOCRIT

SCREENING REQUIREMENTS

Test for anemia by performing or referring for hemoglobin (Hb) or hematocrit (Hct) measurement according to the CHDP schedule for health assessment requirements. See Table 101.1.

Determine if a child is anemic according to the Hb and Hct cutoff values for anemia in children. See Table 701.1.

CONSIDERATIONS FOR REFERRAL, TREATMENT, AND/OR FOLLOW-UP

- Provide nutritional counseling for all children at high risk for anemia based on a nutritional assessment. See Appendix J, “Background Information on Dietary Iron and Counseling Guidelines.”
- See Appendix R, “Iron Replacement Therapy,” for sample dosages of iron replacement for a therapeutic trial for presumptive iron deficiency anemia or treatment for children definitively diagnosed with iron deficiency anemia. Iron supplementation should be administered between meals.
- Recheck Hct or Hb after four weeks of iron replacement therapy and modification of the child’s diet.
- Confirm the diagnosis of iron deficiency anemia based on an increase in hemoglobin concentration of greater than or equal to 1 g/dL or in hematocrit of greater than or equal to 3%.
- Rule out other possible causes of low hematological values if the child has not responded to treatment despite compliance with the iron supplementation and the absence of acute illness. Other laboratory tests should include mean cell volume (MCV), red blood cell distribution width (RDW), and serum ferritin concentration.
- Refer to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (Appendix G) and/or to California Children Services (CCS) (Appendix Q) if appropriate.

RATIONALE

The most common cause of anemia throughout the world is iron deficiency. Its prevalence is highest among young children and women of childbearing age (particularly pregnant women). In

children, iron deficiency anemia can result in developmental delays and behavioral disturbances (e.g., decreased motor activity, social interaction, and attention to tasks). Iron deficiency anemia is also associated with conditions that may independently affect infant and child development (e.g., low birthweight, generalized undernutrition, poverty, and abuse) that need to be taken into account when interventions addressing iron deficiency anemia are developed and evaluated. In addition, iron deficiency anemia contributes to lead poisoning in children by increasing the gastrointestinal tract's ability to absorb heavy metals, including lead. Blood lead screening and testing is required for all young children according to the CHDP protocol described in Section 704, BLOOD LEAD SCREENING.

Because of their low cost and the accuracy, ease, and rapidity in performing them, the tests most commonly used to screen for iron deficiency anemia are Hb concentration and Hct. These measures reflect the amount of functional iron in the body. The concentration of the iron-containing protein Hb in circulating red blood cells is the more direct and sensitive measure. Hct indicates the proportion of whole blood occupied by the red blood cells; it falls only after the Hb concentration falls. Because changes in Hb concentration and Hct occur only at the late stages of iron deficiency, both tests are late indicators of iron deficiency; nevertheless, these tests are essential for determining iron deficiency anemia.

In California the CHDP program monitors the prevalence of anemia through the Pediatric Nutrition Surveillance System (PedNSS) in cooperation with the CDC. PedNSS data for the year 2000 show low Hb or low Hct in approximately 12.6% of children ages 5 to <20 and 13.8% of children aged <5 tested through CHDP. The goal of the CHDP program is to meet the Healthy People 2010 targets of decreasing the frequency of iron deficiency to five percent among children ages one to two, one percent among children ages three to four, and seven percent among non-pregnant females age 12 years and older.

IRON DEFICIENCY ANEMIA

Anemia can usually be prevented by eating a diet which supplies adequate amounts of iron, protein, folic acid, cobalamin (vitamin B12), vitamin C, and other nutrients. Eating non-food items (pica), such as dirt, clay, and laundry starch can lead to iron deficiency and may also be a symptom in the iron deficient and/or lead poisoned patient. Health professionals need to ask specific questions to elicit children's dietary and pica behaviors. Mild iron deficiency (low serum ferritin) should respond within a few months to an increased intake of iron-rich foods which should be continued if the child is to be free of anemia. Children diagnosed with presumptive iron-deficiency anemia require at least a one-month clinical trial of elemental iron along with dietary modification. The specific dosage and treatment should be based on the medical needs of the patient. The most important considerations regarding iron deficiency anemia is that there be continued follow-up and that there is adequate treatment over time.

QUALITY ASSURANCE FOR HEMOGLOBIN OR HEMATOCRIT TESTING

Accurate Hb and Hct testing is essential for proper diagnosis and treatment. Providers who test or examine any material from the human body must obtain a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate to demonstrate compliance with CLIA standards and pertinent California law. The Hb and Hct tests can either be CLIA waived or nonwaived as determined by CLIA guidelines. A waived test is one that is a “simple laboratory procedure which...has an insignificant risk of an erroneous result.” Clinical laboratories conducting only waived tests are exempt from routine federal inspections but must follow the manufacturers’ recommendations for quality assurance and must maintain a CLIA certificate of waiver. A nonwaived test is moderately or highly complex and therefore requires a higher level of knowledge, training, and judgment to be performed properly. Clinical laboratories performing nonwaived tests are required to comply with a series of quality standards (including participation in a proficiency testing program) and to obtain a CLIA certificate of registration or accreditation.

Any FDA approved CLIA waived test system is acceptable for determining hemoglobin or hematocrit. Please refer to the web site <http://www.cap.org/html/lip/waived.html> (College of American Pathologists) for the most current listing of waived test systems for hematology. Nonwaived tests are tests such as color comparators (e.g., BMS Hemoglobinometer™ or American Optical Hb-Meter™) or automated hematology analyzers (e.g., Coulter counter): When providers use CLIA waived tests they are required to perform quality assurance checks according to the manufacturers’ instructions. Providers should also ensure that individuals who draw blood and process Hb or Hct tests also meet CLIA and California requirements and are appropriately trained and rechecked on procedures (e.g., appropriate fingerstick technique).

For additional information on laboratory testing please contact your CHDP program or Department of Health Services, Laboratory Field Services at (210) 833-6000.

Table 701.1 CRITERIA AND RECOMMENDATIONS FOR MANAGING ANEMIA

Condition/Problem	Screening Method	Criteria and Recommendations for Instituting Nutrition Education and Prevention	Criteria and Recommendations for Diagnosis, Treatment, and Follow-up																																																																																		
Anemia	Hemoglobin (gm/dl) Hematocrit (%)	<p>Criteria:</p> <table border="1"> <thead> <tr> <th>Age (Years)</th> <th>Sex</th> <th>*Hgb Below</th> <th>*Hct Below</th> </tr> </thead> <tbody> <tr> <td>< 2</td> <td>Both</td> <td>11.5</td> <td>35</td> </tr> <tr> <td>2 < 5</td> <td>Both</td> <td>11.5</td> <td>35</td> </tr> <tr> <td>5 < 8</td> <td>Both</td> <td>12.0</td> <td>36</td> </tr> <tr> <td>8 < 12</td> <td>Both</td> <td>12.0</td> <td>36</td> </tr> <tr> <td rowspan="2">12 < 15</td> <td>Females</td> <td>12.5</td> <td>38</td> </tr> <tr> <td>Males</td> <td>13.0</td> <td>39</td> </tr> <tr> <td rowspan="2">15 < 18</td> <td>Females</td> <td>12.5</td> <td>38</td> </tr> <tr> <td>Males</td> <td>14.0</td> <td>42</td> </tr> <tr> <td rowspan="2">> 18</td> <td>Females</td> <td>12.5</td> <td>38</td> </tr> <tr> <td>Males</td> <td>14.0</td> <td>42</td> </tr> </tbody> </table>	Age (Years)	Sex	*Hgb Below	*Hct Below	< 2	Both	11.5	35	2 < 5	Both	11.5	35	5 < 8	Both	12.0	36	8 < 12	Both	12.0	36	12 < 15	Females	12.5	38	Males	13.0	39	15 < 18	Females	12.5	38	Males	14.0	42	> 18	Females	12.5	38	Males	14.0	42	<p>Criteria:</p> <table border="1"> <thead> <tr> <th>Age (Years)</th> <th>Sex</th> <th>*Hgb Below</th> <th>*Hct Below</th> </tr> </thead> <tbody> <tr> <td>< 2</td> <td>Both</td> <td>11.0</td> <td>32.9</td> </tr> <tr> <td>2 < 5</td> <td>Both</td> <td>11.1</td> <td>33.0</td> </tr> <tr> <td>5 < 8</td> <td>Both</td> <td>11.5</td> <td>34.5</td> </tr> <tr> <td>8 < 12</td> <td>Both</td> <td>11.9</td> <td>35.4</td> </tr> <tr> <td rowspan="2">12 < 15</td> <td>Females</td> <td>11.8</td> <td>36</td> </tr> <tr> <td>Males</td> <td>12.5</td> <td>37.3</td> </tr> <tr> <td rowspan="2">15 < 18</td> <td>Females</td> <td>12.0</td> <td>36</td> </tr> <tr> <td>Males</td> <td>13.3</td> <td>39.7</td> </tr> <tr> <td rowspan="2">> 18</td> <td>Females</td> <td>12.0</td> <td>36</td> </tr> <tr> <td>Males</td> <td>13.5</td> <td>39.9</td> </tr> </tbody> </table>	Age (Years)	Sex	*Hgb Below	*Hct Below	< 2	Both	11.0	32.9	2 < 5	Both	11.1	33.0	5 < 8	Both	11.5	34.5	8 < 12	Both	11.9	35.4	12 < 15	Females	11.8	36	Males	12.5	37.3	15 < 18	Females	12.0	36	Males	13.3	39.7	> 18	Females	12.0	36	Males	13.5	39.9
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	Nutrition Screening Tools	<ul style="list-style-type: none"> • Common Causes of Anemia <ul style="list-style-type: none"> ❖ Inappropriate milk intake for age. ❖ Inadequate dietary iron intake. <p>Recommendations:</p> <ul style="list-style-type: none"> • Nutrition counselling. • Refer eligible children to Supplemental Nutrition Program, Women, Infants, Children (WIC). 	<p>Common Causes of Anemia</p> <ul style="list-style-type: none"> ❖ Inappropriate milk intake for age. ❖ Inadequate intake of iron, cobalamin (B12), folic acid, or vitamin C and other nutrients. <p>Recommendations:</p> <ul style="list-style-type: none"> • Refer eligible children to WIC • Verify accuracy of Hgb/Hct by verifying equipment is accurate and blood draw technique is correct. • Refer to Appendix E (Equipment Guide for Measuring and Weighing) • One month of clinical trial of elemental iron along with nutrition counselling. • Recheck Hgb/Hct to monitor resolution of anemia. If anemia does not improve, further laboratory testing, diagnosis is indicated. • Refer to registered dietitian for medical nutrition therapy when provider determines necessary. • Screen/test for pica, lead poisoning. 																																																																																		

Note: Refer to Appendix J for Background Information on Dietary Iron and Counseling Guidelines.

* Pediatric Nutrition Surveillance System (PedNSS) data 1995-2000

URINE DIPSTICK OR URINALYSIS

SCREENING REQUIREMENTS

Test urine* at each health assessment visit starting at age four to five years.

Test* earlier than age four to five years if the child has a history of a urinary tract infection or complaints of frequency, urgency, or dysuria.

CONSIDERATIONS FOR REFERRAL, TREATMENT, AND/OR FOLLOW-UP

Arrange or initiate further evaluation, diagnosis, and treatment if the child has any of the following conditions, but not limited to:

A positive dipstick leukocyte esterase test or other urinalysis showing any abnormal values.

Persistent bed wetting beyond age five years.

RATIONALE

A screening urinalysis can detect many types of abnormalities in the urine, including presence of glucose, protein, red and white blood cells, bacteria, and bacterial breakdown products. In asymptomatic children, screening for red blood cells and protein is generally not very productive because of the transient and benign nature of the disorders causing them. Screening for glucosuria is also of questionable utility because the onset of glucosuria and the onset of the symptoms for diabetes mellitus occur almost simultaneously. Screening for indicators of occult infection, such as white blood cells and bacteria, may be beneficial as a means of starting early treatment. The urine specimen is most efficiently screened for bacteriuria by using a dipstick leukocyte esterase test. The sensitivity and specificity (each approximately 80 percent) of the leukocyte esterase test is roughly equivalent to that obtained by more labor-intensive microscopic analysis.

*Any FDA approved, CLIA waived test system is acceptable for testing urine. The web site <http://www.cap.org/html/lip/waived.html> (College of American Pathologists) lists the most current test systems for urinalysis. Provider-based clinical laboratories conducting waived tests (simple laboratory procedures with an insignificant risk of an erroneous result) must follow the manufacturers' recommendations for quality assurance and must maintain a CLIA certificate of waiver. Provider-based clinical laboratories performing nonwaived tests (moderately or highly complex procedures) are required to comply with a series of quality standards and to obtain and maintain a CLIA certificate of registration or accreditation.

Iron Replacement Therapy
Medical Management Of Childhood Anemia
Sample Iron Doses

For Infants

Use Ferrous Sulfate drops, (Fer In Sol drops) 75 mg (15mgFe)/0.6ml

Weight kg (lbs)	Ferrous Sulfate	# of Droppers	Frequency
5 - 7 kg (11 - 15 lbs)	0.6 ml	1	QD
7 - 10 kg (15 - 22 lbs)	0.9 ml	1.5	QD
10 - 13 kg (22 - 28 lbs)	1.2 ml	2	QD
Note: 13 - 16 kg (28 - 45 lb), give 2 droppers QD or change to Ferrous Sulfate Elixir			

For Toddlers and Older Children

Use Ferrous Sulfate Elixir, e.g., Feosol Elixir, 220 mg/5ml elixir (44mg elemental Fe/5 ml)

Weight kg (lbs)	Ferrous Sulfate Elixir	Frequency
10 - 11 kg (22 - 24 lbs)	3.0 ml	QD
11 - 13 kg (24 - 29 lbs)	4.0 ml	QD
13 - 17 kg (29 - 38 lbs)	5.0 ml	QD
17 - 24 kg (38 - 53 lbs)	3.0 ml (option 5.0 ml QD)	BID
24 - 31 kg (53 - 68 lbs)	4.0 ml (option 5.0 ml QD)	BID
> 32 kg (over 68 lbs)	dose as for 24 - 31 kg or change to Ferrous Sulfate Tablets 195 mg (39 mg Fe) 1 tablet po BID or 325 mg (60 mg Fe) 1 tablet po QD	

Note: These sample doses provide 2.5 - 3.5 mg/kg/day of iron. Some providers prefer higher doses (3-6 mg/kg/day) which may be associated with more GI side effects. If using iron as therapeutic trial, repeat the anemia screening in 4 weeks. If iron deficiency anemia is confirmed based on an increase in hemoglobin concentration of greater than or equal to 1g/dL or in hematocrit of greater than or equal to 3% continue iron treatment for 2 more months, then recheck. Reassess Hb or Hct in 6 months after successful treatment is completed. Usual duration of iron replacement is 3 months*.

* U.S Department of Health and Human Services, Centers for Disease and Prevention (CDC)
 Atlanta, Georgia 1998.