Equipment Packet: Bililights and Phototherapy

UMDNS #: 17515

Date of Creation: November 10, 2015

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of bililights and bilirubinometers.

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1. Operation and Use of Bililights

Featured in this Section:

Malkin, Robert. “Phototherapy Lights.” *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

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Wikipedia. “Neonatal Jaundice.” *Wikipedia.* Retrieved from: https://en.wikipedia.org/wiki/Neonatal_jaundice

Phototherapy units, hyperbilirubinemia

Brief Introduction to Phototherapy

UMDNS		GMDN	
17515	Phototherapy units, visible light, hyperbilirubinemia	35475	Blanket/pad infant phototherapy unit
		35239	Overhead infant phototherapy unit

Other common names:
Bilirubin lamps; fiberoptic phototherapy blankets; neonatal phototherapy units

Health problem addressed

Devices used to treat hyperbilirubinemia, characterized by high bilirubin concentrations in the blood. Bilirubin, a product of hemoglobin breakdown, remains in the body until the liver can convert it to a form that can be excreted. Jaundice, a yellowish discoloration of the skin, eyes, and mucous membranes, results when bilirubin levels in the blood are too high. High bilirubin levels can be caused by the inability of an immature liver to process high levels of bilirubin, particularly in neonates.

Product description

Phototherapy units consist of a light source and a means of allowing the light to radiate the infant. Devices using overhead lamps can be freestanding on casters, ceiling or wall mounted, or attached to infant radiant warmers or infant incubators; some units have height and hood angle adjustments. Bassinet-style units, in which the infant is placed in a plastic bassinet containing a bank of lights in an overhead case, are also available. Fiberoptic phototherapy pad systems use a tungsten-halogen bulb in a metal case, a flexible fiberoptic cable, and a light-emitting plastic pad. Filtered blue light is delivered from the source through the fiberoptic cable and emitted from the sides and ends of the fibers inside the pad, which is wrapped around the infant.

Principles of operation

Visible light, specifically the blue-light wavelengths of approximately 420 to 500 nanometers, photochemically reduces bilirubin to water-soluble products that can be excreted. The peak absorption wavelength at which bilirubin breaks down is approximately 458 nm. By exposing patients to light of this wavelength range, hyperbilirubinemia can be treated. Irradiance level is controlled by light-intensity switches for both overhead lamps and fiberoptic units and by the distance between the light source and the patient. (Decreasing the distance between the patient and the light source increases the irradiance level.) A radiometer with an appropriate bandwidth is used to measure the irradiance that reaches the patient during phototherapy.

Operating steps

- Eye mask is placed on unclothed infant and place infant in bassinet.
- Depending on configuration, lamp distance is set depending on intensity of therapy desired, or infant is wrapped in fiberoptic pad.
- Treatment typically lasts 1-3 days.

Reported problems

Ultraviolet (280 to 400 nm) or near-infrared (780 to 1,400 nm) radiation must be filtered because at high enough levels, both types of radiation can damage the eyes and skin. Known common side effects of phototherapy include changes in body temperature, insensible water loss, and diarrhea. With fiberoptic

units, a blanket can be wrapped around the infant and fiberoptic pad to minimize fluctuations in body temperature.

Use and maintenance

User(s): Nurse; clinician; medical staff

Maintenance: Biomedical engineering staff and/or service contract with the manufacturer or third-party organization

Training: Initial training by manufacturer; operator's manuals; user's guide

Environment of use

Settings of use: Hospital; birthing center

Requirements: Line power

Product specifications

Approx. dimensions (mm): 1200 x 650 x 250 for overhead lamp type; 200 x 350 x 150 for fiberoptic type

Approx. weight (kg): 36 for overhead lamp type; 2 for fiberoptic type

Consumables: Light bulbs; disposable pad covers

Price range (USD): 400-7,600 (2,000 typical); price covers all types and variations

Typical product life time: 10 years

Shelf life (consumables): NA

Types and variations

- Overhead lamps
- Fiberoptic blanket systems

WHO. "Phototherapy units, hyperbilirubinemia." From the page: "Hospital medical equipment: Data Sheets 2012." WHO. Retrieved from: http://www.who.int/medical_devices/innovation/core_equipment/en/index1.html

Bilirubinometer **Brief Introduction to Bilirubinometers**

UMDNS		GMDN	
15109	Bilirubinometers	47988	Bilirubinometer
16166	Bilirubinometers, Cutaneous	16166	Cutaneous bilirubinometer

Other common names:
Analyzers, Bilirubin; Bilirubin Analyzers; Jaundice Meters; Indirect Bilirubinometers

Health problem addressed

In healthy full-term neonates, bilirubin can rise to peak levels of 5 to 13 mg/dL between the second and fifth days of life before decreasing to normal levels between the fifth and seventh days. This produces jaundice, a yellowish discoloration of the skin, eyes, and mucous membranes. Monitoring bilirubin concentration is also important in children and in adults where elevated levels may indicate a pre-hepatic, hepatic, or post-hepatic metabolic disorder.

Product description

These devices come in a variety of physical configurations. They may be relatively small, single-purpose hand-held instruments that are simple to operate and are designed to measure the concentration of bilirubin in the blood. They are often located in neonatal intensive care units for rapid on-site bilirubin analysis, which is essential for determining a proper treatment method. Bilirubinometers may also be configured as larger benchtop analyzers or stand-alone units.

Principles of operation

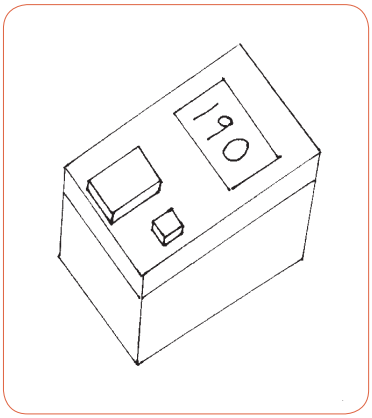
Bilirubin concentrations are determined either by whole blood or serum analysis using spectrophotometric methods or by skin-reflectance measurements. The three methods of spectrophotometric analysis are the direct spectrophotometric method, the Malloy-Evelyn method, and the Jendrassik-Grof method.

Operating steps

Blood samples are required for spectrophotometric analysis. The analysis technique depends on both the type or types of bilirubin being measured and the age of the patient (neonate versus child or adult). Cutaneous bilirubinometers do not require a blood sample. A light-emitting sensor is placed on the infant's skin (optimally on the forehead or sternum). The reflected light is split into two beams by a dichroic mirror, and wavelengths of 455 nm and 575 nm are measured by optical detectors.

Reported problems

Rapid changes in hydration (body water content) during therapy can cause fluctuations in blood bilirubin concentrations, making assay results uncertain. Photo-oxidation (light-induced breakdown) of bilirubin occurs if samples are exposed to light for more than a few hours. Therefore, blood samples should be protected from exposure to light.



Use and maintenance

User(s): Operator, medical staff

Maintenance: Medical staff; technician; biomedical or clinical engineer

Training: Initial training by manufacturer and manuals

Environment of use

Settings of use: Hospital; clinic

Requirements: Stable power source

Product specifications

Approx. dimensions (mm): 110 x 150 x 200

Approx. weight (kg): 3.4

Consumables: NA

Price range (USD): 3,100 - 7,000

Typical product life time (years): 6 to 8

Shelf life (consumables): NA

Types and variations

Benchtop; stand-alone; handheld

WHO. "Bilirubinometer." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

Neonatal jaundice

Introduction to Neonatal Jaundice

From Wikipedia, the free encyclopedia

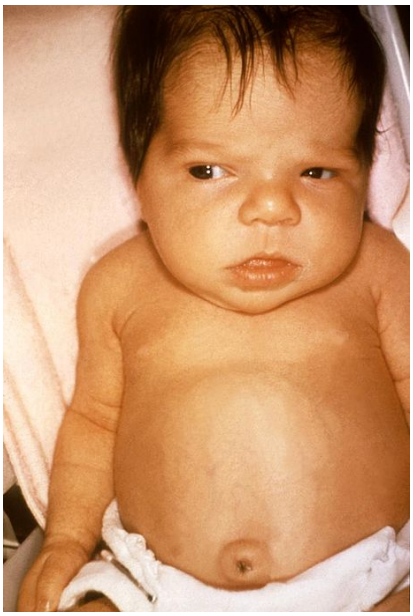
Neonatal jaundice or **Neonatal hyperbilirubinemia**, or **Neonatal icterus** (from the Greek word ἴκτερος), attributive adjective: **icteric**, is a yellowing of the skin and other tissues of a newborn infant. A bilirubin level of more than 85 µmol/l (5 mg/dL) leads to a jaundiced appearance in neonates whereas in adults a level of 34 µmol/l (2 mg/dL) is needed for this to occur. In newborns, jaundice is detected by blanching the skin with pressure applied by a finger so that it reveals underlying skin and subcutaneous tissue.[1] Jaundiced newborns have yellow discoloration of the white part of the eye, and yellowing of the face, extending down onto the chest.

Neonatal jaundice can make the newborn sleepy and interfere with feeding. Extreme jaundice can cause permanent brain damage from kernicterus.

In neonates, the yellow discoloration of the skin is first noted in the face and as the bilirubin level rises proceeds caudal to the trunk and then to the extremities.[2] This condition is common in newborns affecting over half (50–60%) of all babies in the first week of life.[3]

Infants whose palms and soles are yellow, have serum bilirubin level over 255 µmol/l (15 mg/dL) (more serious level). Studies have shown that trained examiners assessment of levels of jaundice show moderate agreement with icterometer bilirubin measurements.[2] In infants, jaundice can be measured using invasive or non-invasive methods.

Neonatal jaundice



Jaundice in newborn

Classification and external resources

Specialty	Pediatrics
ICD-10	P58 (http://apps.who.int/classifications/icd10/browse/2015/en#/P58), P59 (http://apps.who.int/classifications/icd10/browse/2015/en#/P59)
ICD-9-CM	773 (http://www.icd9data.com/getICD9Code.ashx?icd9=773), 774 (http://www.icd9data.com/getICD9Code.ashx?icd9=774)
DiseasesDB	8881 (http://www.diseasesdatabase.com/ddb8881.htm)
MedlinePlus	001559 (http://www.nlm.nih.gov/medlineplus/ency/article/001559.htm)
eMedicine	ped/1061 (http://www.emedicine.com/ped/topic1061.htm)
Patient UK	Neonatal jaundice (http://patient.info/doctor/neonatal-jaundice-pro)
MeSH	D007567 (https://www.nlm.nih.gov/cgi/mesh/2015/MB_cgi?field=uid&term=D007567)

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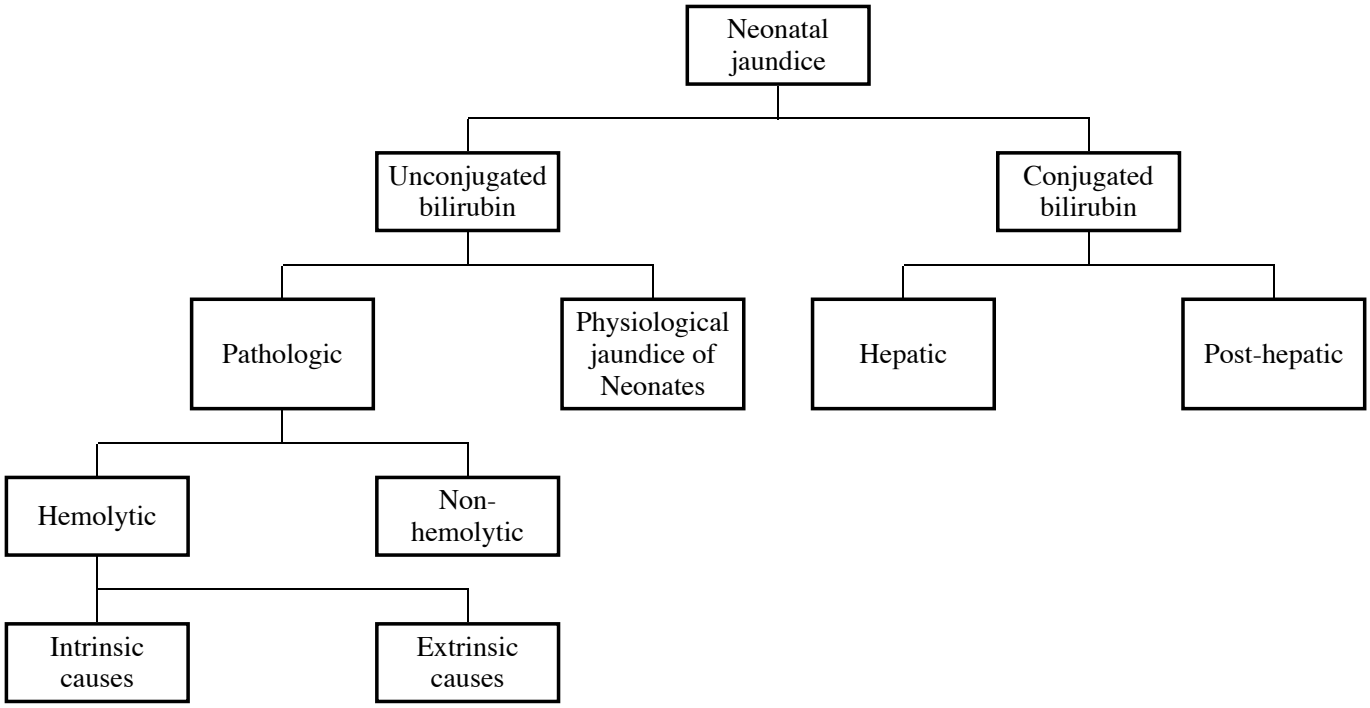
Causes

Wikipedia. “Neonatal Jaundice.” Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Neonatal_jaundice

In neonates, jaundice tends to develop because of two factors - the breakdown of fetal hemoglobin as it is replaced with adult hemoglobin and the relatively immature metabolic pathways of the liver, which are unable to conjugate and so excrete bilirubin as quickly as an adult. This causes an accumulation of bilirubin in the blood (hyperbilirubinemia), leading to the symptoms of jaundice.

If the neonatal jaundice does not clear up with simple phototherapy, other causes such as biliary atresia, Progressive familial intrahepatic cholestasis, bile duct paucity, Alagille syndrome, alpha 1-antitrypsin deficiency, and other pediatric liver diseases should be considered. The evaluation for these will include blood work and a variety of diagnostic tests. Prolonged neonatal jaundice is serious and should be followed up promptly.

Severe neonatal jaundice may indicate the presence of other conditions contributing to the elevated bilirubin levels, of which there are a large variety of possibilities (see below). These should be detected or excluded as part of the differential diagnosis to prevent the development of complications. They can be grouped into the following categories:



Unconjugated

Hemolytic

Intrinsic causes of hemolysis

- Membrane conditions
  - Spherocytosis
  - Hereditary elliptocytosis
- Systemic conditions
  - Sepsis
  - Arteriovenous malformation
- Enzyme conditions
  - Glucose-6-phosphate dehydrogenase deficiency (also called G6PD deficiency)
  - Pyruvate kinase deficiency
- Globin synthesis defect
  - sickle cell disease
  - Alpha-thalassemia, e.g. HbH disease

Extrinsic causes of hemolysis

Wikipedia. "Neonatal Jaundice." Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Neonatal_jaundice

- Alloimmunity (The neonatal or cord blood gives a positive direct Coombs test and the maternal blood gives a positive indirect Coombs test)
  - Hemolytic disease of the newborn (ABO)[1]
  - Rh disease[1]
  - Hemolytic disease of the newborn (anti-Kell)
  - Hemolytic disease of the newborn (anti-Rhc)
  - Other blood type mismatches causing hemolytic disease of the newborn

Non-hemolytic causes

- Breast milk jaundice
- Cephalohematoma
- Polycythemia
- Urinary tract infection
- Sepsis
- Hypothyroidism
- Gilbert's syndrome
- Crigler-Najjar syndrome
- High GI obstruction

Conjugated (Direct)

Liver causes

- Infections
  - Sepsis
  - Hepatitis A
  - Hepatitis B
  - TORCH infections
- Metabolic
  - Galactosemia
  - Alpha-1-antitrypsin deficiency, which is commonly missed, and must be considered in DDx
  - Cystic fibrosis
  - Dubin-Johnson Syndrome
  - Rotor syndrome
- Drugs
- Total parenteral nutrition
- Idiopathic

Post-liver

- Biliary atresia or bile duct obstruction
  - Alagille syndrome
  - Choledochal cyst

Non-organic causes

Breastfeeding failure jaundice

"Breastfeeding failure jaundice" or "lack of breastfeeding jaundice," is caused by insufficient breast milk intake,[4] resulting in inadequate quantities of bowel movements to remove bilirubin from the body. This can usually be ameliorated by frequent breastfeeding sessions of sufficient duration to stimulate adequate milk production.

Breast milk jaundice

Whereas breast *feeding* jaundice is a mechanical problem, breast *milk* jaundice is a biochemical occurrence and the higher bilirubin possibly acts as an antioxidant. Breast milk jaundice occurs later in the newborn period, with the bilirubin level usually peaking in the sixth to 14th days of life. This late-onset jaundice may develop in up to one third of healthy breastfed infants.[5]

- First, at birth, the gut is sterile, and normal gut flora takes time to establish. The bacteria in the adult gut convert conjugated bilirubin to stercobilinogen which is then oxidized to stercobilin and excreted in the stool. In the absence of sufficient bacteria, the bilirubin is de-conjugated by brush border β-glucuronidase and reabsorbed. This process of re-absorption is called enterohepatic circulation. It has been suggested that bilirubin uptake in the gut (enterohepatic circulation) is increased in breast fed babies, possibly as the result of increased levels of epidermal growth factor (EGF) in breast milk.[6] Breast milk also contains glucoronidase which will increase deconjugation and enterohepatic recirculation of bilirubin.

- Second, the breast-milk of some women contains a metabolite of progesterone called 3-alpha-20-beta pregnanediol. This substance inhibits the action of the enzyme uridine diphosphoglucuronic acid (UDPGA) glucuronyl transferase responsible for conjugation and subsequent excretion of bilirubin. In the newborn liver, activity of glucuronyl transferase is only at 0.1-1% of adult levels, so conjugation of bilirubin is already reduced. Further inhibition of bilirubin conjugation leads to increased levels of bilirubin in the blood.[7] However, these results have not been supported by subsequent studies.[8]

- Third, an enzyme in breast milk called lipoprotein lipase produces increased concentration of nonesterified free fatty acids that inhibit hepatic glucuronyl transferase, which again leads to decreased conjugation and subsequent excretion of bilirubin.[9]

Physiological jaundice

Most infants develop visible jaundice due to elevation of unconjugated bilirubin concentration during their first week. This common condition is called physiological jaundice. This pattern of hyperbilirubinemia has been classified into two functionally distinct periods.

Phase one

1. Term infants - jaundice lasts for about 10 days with a rapid rise of serum bilirubin up to 204 μmol/l (12 mg/dL).
2. Preterm infants - jaundice lasts for about two weeks, with a rapid rise of serum bilirubin up to 255 μmol/l (15 mg/dL).

Phase two - bilirubin levels decline to about 34 μmol/l (2 mg/dL) for two weeks, eventually mimicking adult values.

1. Preterm infants - phase two can last more than one month.
2. Exclusively breastfed infants - phase two can last more than one month.

Mechanism involved in physiological jaundice are mainly:

- Relatively low activity of the enzyme glucuronosyltransferase which normally converts unconjugated bilirubin to conjugated bilirubin that can be excreted into the gastrointestinal tract.[10] Before birth, this enzyme is actively down-regulated, since bilirubin needs to remain unconjugated in order to cross the placenta to avoid being accumulated in the fetus.[11] After birth, it takes some time for this enzyme to gain function.
- Shorter life span of fetal red blood cells,[10] being approximately 80 to 90 days in a full term infant,[12] compared to 100 to 120 days in adults.
- Relatively low conversion of bilirubin to urobilinogen by the intestinal flora, resulting in relatively high absorption of bilirubin back into the circulation.[10]

Diagnosis

Clinical Assessment

This method is less accurate and more subjective in estimating jaundice.

Ingram icterometer: In this method a piece of transparent plastic known as **Ingram icterometer** is used. Ingram icterometer is painted in five transverse strips of graded yellow lines. The instrument is pressed against the nose and the yellow colour of the blanched skin is matched with the graded yellow lines and bilirubin level is assigned.

Transcutaneous bilirubinometer: This is hand held, portable and rechargeable but expensive and sophisticated. When pressure is applied to the photoprobe, a xenon tube generates a strobe light, and this light passes through the subcutaneous tissue. The reflected light returns through the second fiber optic bundle to the spectrophotometric module. The intensity of the yellow color in this light, after correcting for the hemoglobin, is measured and instantly displayed in arbitrary units.

Any of the following features characterizes pathological jaundice:

1. Clinical jaundice appearing in the first 24 hours or greater than 14 days of life.
2. Increases in the level of total bilirubin by more than 8.5 μmol/l (0.5 mg/dL) per hour or (85 μmol/l) 5 mg/dL per 24 hours.
3. Total bilirubin more than 331.5 μmol/l (19.5 mg/dL) (hyperbilirubinemia).
4. Direct bilirubin more than 34 μmol/l (2.0 mg/dL).

The aim of clinical assessment is to distinguish physiological from pathological jaundice. The signs which help to differentiate pathological jaundice of neonates from physiological jaundice of neonates are the presence of intrauterine growth restriction, stigma of intrauterine infections (e.g. cataracts, small head, and enlargement of the liver and spleen), cephalohematoma, bruising, signs of bleeding in the brain's ventricles. History of illness is noteworthy. Family history of jaundice and anemia, family history of neonatal or early infant death due to liver disease, maternal illness suggestive of viral infection (fever, rash or lymphadenopathy), maternal drugs (e.g. sulphonamides, anti-malarials causing red blood cell destruction in G6PD deficiency) are suggestive of pathological jaundice in neonates.[13]

Treatment

The bilirubin levels for initiative of phototherapy varies depends on the age and health status of the newborn. However, any newborn with a total serum bilirubin greater than 359 μmol/l (21 mg/dL) should receive phototherapy.[14]

Phototherapy

The use of phototherapy was first discovered, accidentally, at Rochford Hospital in Essex, England. The ward sister (Charge Nurse) of the premature baby unit firmly believed that the infants under her care benefited from fresh air and sunlight in the courtyard. Although this led to the first noticing of jaundice being improved with sunlight, further studies only progressed when a vial of blood sent for bilirubin measurement sat on a windowsill in the lab for several hours. The results indicated a much lower level of bilirubin than expected based on the patient's visible jaundice. Further investigation led to the determination that blue light, wavelength of 420-480nm (peak 458nm), oxidized the bilirubin to biliverdin, a soluble product that does not contribute to kernicterus. Although some pediatricians began using phototherapy in the United Kingdom following Dr. Cremer's publishing the above facts in the *Lancet* in 1958, most hospitals only began to regularly use phototherapy ten years later when an American group independently made the same discovery.[15][16]

Infants with neonatal jaundice are treated with colored light called phototherapy. Physicians randomly assigned 66 infants 35 weeks of gestation to receive phototherapy. After 15±5 the levels of bilirubin, a yellowish bile pigment that in excessive amounts causes jaundice, were decreased down to 0.27±0.25 mg/dl/h in the blue light. This suggests that blue light therapy helps reduce high bilirubin levels that cause neonatal jaundice.[17]

newborn infant undergoing (white light) phototherapy to treat neonatal jaundice

Exposing infants to high levels of colored light changes trans-bilirubin to the more water-soluble cis-form which is excreted in the bile. Scientists studied 616 capillary blood samples from jaundiced newborn infants. These samples were randomly divided into three groups. One group contained 133 samples and would receive phototherapy with blue light. Another group contained 202 samples would receive room light, or white light. The final group contained 215 samples, and were left in a dark room. The total bilirubin levels were checked at 0, 2, 4, 6, 24, and 48 hours. There was a significant decrease in bilirubin in the first group exposed to phototherapy after two hours, but no change occurred in the white light and dark room group. After 6 hours, there was a significant change in bilirubin level in the white light group but not the dark room group. It took 48 hours to record a change in the dark room group's bilirubin level. Phototherapy is the most effective way of breaking down a neonate's bilirubin.[18]

Phototherapy works through a process of isomerization that changes trans-bilirubin into the water-soluble cis-bilirubin isomer.[19][20]

In phototherapy, blue light is typically used because it is more effective at breaking down bilirubin (Amato, Inaebnit, 1991). Two matched groups of newborn infants with jaundice were exposed to intensive green or blue light phototherapy. The efficiency of the treatment was measured by the rate of decline of serum bilirubin, which in excessive amounts causes jaundice, concentration after

6, 12 and 24 hours of light exposure. A more rapid response was obtained using the blue lamps than the green lamps. However, a shorter phototherapy recovery period was noticed in babies exposed to the green lamps(1). Green light is not commonly used because exposure time must be longer to see dramatic results(1).

Ultraviolet light therapy may increase the risk of skin moles, in childhood. While an increased number of moles is related to an increased risk of skin cancer,[21][22][23] it is not ultraviolet light that is used for treating neonatal jaundice. Rather, it is simply a specific frequency of blue light that does not carry these risks.

Increased feedings help move bilirubin through the neonate's metabolic system.[24]

The light can be applied with overhead lamps, which means that the baby's eyes need to be covered, or with a device called a Biliblanket, which sits under the baby's clothing close to its skin.

Exchange transfusions

Much like with phototherapy the level at which exchange transfusion should occur depends on the health status and age of the newborn. It should however be used for any newborn with a total serum bilirubin of greater than 428 μmol/l (25 mg/dL).[14]

Complications

Prolonged hyperbilirubinemia (severe jaundice) can result into chronic bilirubin encephalopathy (kernicterus).[25][26] Quick and accurate treatment of neonatal jaundice helps to reduce the risk of neonates developing kernicterus.[27]

Infants with kernicterus may have a fever[28] or seizures.[29] High pitched crying is an effect of kernicterus. Scientists used a computer to record and measure cranial nerves 8, 9 and 12 in 50 infants who were divided into two groups equally depending upon bilirubin concentrations. Of the 50 infants, 43 had tracings of high pitched crying.[30]

Exchange transfusions performed to lower high bilirubin levels are an aggressive treatment.[31]

Guidelines

American Academy of Pediatrics has issued guidelines for managing this disease, which can be obtained for free.[32]
National Institute for Health and Care Excellence (NICE) has issued guidelines for the recognition and treatment of neonatal jaundice in the United Kingdom.[33]

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External links

- Neonatal Hyperbilirubinemia Management and Learning Tool for Healthcare Providers (http://neonatalhyperbilirubinemia.org)
- Jaundice in the first two weeks of life (http://www.netsvic.org.au/nets/handbook/?doc_id=458)
- BiliTool - Hyperbilirubinemia Risk Assessment for Newborns (http://bilitool.org)
- Children's Liver Disease Foundation - information on jaundice in babies (http://www.yellowalert.org)
- Neonatal jaundice (http://edaff.siumed.edu/peds/Neonatal_Jaundice.pdf) - Southern Illinois University School of Medicine
- Neonatal Jaundice (http://www.neonataljaundice.net/) at www.neonataljaundice.net (http://www.neonataljaundice.net/)
- Using LED to cure Neonatal Jaundice (http://themedicaid.in/index.php/phototherapy) at Medicaid Phototherapy Unit (http://themedicaid.in/index.php/phototherapy)

Wikipedia. “Neonatal Jaundice.” Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Neonatal_jaundice

Operation and Use of Phototherapy Lights

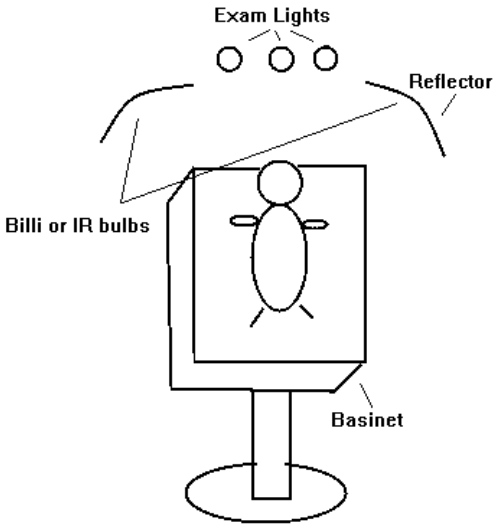
Equipment found in the OR, ICU and ER

2.12 Phototherapy lights

2.12.1 Clinical Use and Principles of Operation

The buildup of bilirubin in an infant's blood, caused by decreased liver functions, can cause long term damage to the child. Bilirubin buildup causes the patients' coloring to range from yellow to orange to red depending upon the level of bilirubin in the system. By exposing the patient to light with wavelengths between 425 and 475 nm, the bilirubin is broken down, and then eventually excreted from the body.

The phototherapy unit, or bili-lights, as they are more commonly called, is simply a strong source of light in the correct wavelength. The baby sits in a basinet below the lights for 20 minutes or more, depending on what the physician prescribes (see figure). The light is strong enough that it can damage the retina. So, the patients' eyes must be protected from the light when using the bili-light.



Phototherapy lights are common in the developing world. However, the bulbs are often broken or ineffective. Exam lights are often included as well as heating (IR) lamps.

2.12.2 Common Problems

The most common problem is a broken or missing light bulb. There is little else that can go wrong. There are many substitute light sources. The use of Florissant brand tubes or Daylight blue bulbs is quite common. The "Gro-Lux" light, also used by indoor gardeners was the most common form of treatment. Unfortunately the Gro-Lux tubes degrade and have to be replaced after about 200 hours of use to keep the light in the proper wavelength range. The same light spectrum is used in a PUMA unit to treat certain skin disorders in adults. The light bulbs in tanning beds are also in the correct wavelength range.

2.12.3 Suggested Minimal Testing

If the light turns on and is still in the correct wavelength range, then the unit can be used. To verify that the light is in the correct range, you need a light meter and a filter. A photographer's light meter can be used if the proper filter is at hand. If you have time, you can check the light source by leaving your arm exposed to the light for 30 minutes. The next day, that part of your skin should be tan, but not burned.

If you have replaced the light bulb, or have built a phototherapy unit from light bulbs that you purchased (gro-lux or tanning bed lights, for example), then you must be sure that the lights are not too intense for the patient. Again the ideal test is a light meter and a proper filter. However, you can use the arm-tanning test mentioned above. Start with 5 minutes to be sure that you do not get burned. Test longer and longer intervals until you can withstand 30 minutes without burning, but receiving a significant tan. Explain your testing to the staff so that they know that it is safe for up to 30 minutes, but that you haven't tested it for longer exposures.

If the light is working and you have a meter, you can also check that the intensity is consistent over the entire surface of the patient.

2. Diagrams and Schematics of Bililights

Featured in this Section:

WHO. “Bilirubinometer.” From the publication: “WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 1: WHO Specification: Bilirubinometer

MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	**Bilirubinometer**
3	Specific type or variation (optional)	N/A
4	GMDN name	Bilirubinometer IVD
5	GMDN code	47988
6	GMDN category	06 In vitro diagnostic devices
7	UMDNS name	Bilirubinometers
8	UMDNS code	15109
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Bilirubin analyser; Jaundice meter; Meter, jaundice
11	Alternative code/s (optional)	S 15109; S 43856; S 44219
12	Keywords (optional)	Bilirubin, Jaundice, Analyzer
13	GMDN/UMDNS definition (optional)	A mains electricity (AC-powered) laboratory instrument designed to determine, by direct or indirect measurement, the concentration of bilirubin in the blood or other clinical specimen most commonly to rapidly assess hyperbilirubinemia in neonates. It typically performs the measurement using spectrophotometry or haemofluorometry.
PURPOSE OF USE		
14	Clinical or other purpose	Determining the concentration of bilirubin in the blood or other clinical specimen, most commonly to rapidly assess hyperbilirubinemia in neonates. (Bilirubin, a product of haemoglobin breakdown, remains in the body until the liver can convert it to a form that can be excreted. Jaundice, a yellowish discoloration of the skin, eyes, and mucous membranes, is a major symptom noticed when bilirubin levels rise above 5 mg/dl).
15	Level of use (if relevant)	Health Centre, District Hospital, Provincial Hospital and Specialized Hospital
16	Clinical department/ward(if relevant)	Obstetrics / Neonatal care / Neonatal Intensive Care Unit (NICU) / Laboratory
17	Overview of functional requirements	1. Measures bilirubin concentration in a blood sample. 2. Displays and prints total bilirubin concentration (conjugated bilirubin level is optional).
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	1. Total bilirubin concentration measurable (at least) in range of 0 to 30 mg/dl. 2. Time for total concentration measurement: ≤ 5 seconds. 3. Sample volume of < 100 µl required, automatic calibration facility, either integral printer for readings or interface with external printer. 4. Able to perform at least 300 measurements with fully charged battery. 5. Measurement unit: mg/dL or µmol/L (user selectable). 6. Measuring range of at least 0.0 to 25 mg/dl or 0 to 425 µmol/lt. 7. Accuracy ± 1.5 mg/dl or ± 25.5 µmol/lt or better. 8. Not need any disposable or consumable to operate. 9. Light source life of 150K measurements or more.
19	Displayed parameters	Backlit display with easy viewing in all ambient light levels. Electronic and printed readout.

WHO. "Bilirubinometer." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	N/A
22	Mobility, portability(if relevant)	Easy and safe transport to be possible by hand, stable when table-top mounted. Hand held compact, lightweight, easy to use.
23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	1. Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. 2. Electrical protection by resettable overcurrent breakers or replaceable fuses fitted in both live and neutral lines. 3. Resettable overcurrent mains fuse to be incorporated. 4. Mains cable to be at least 3 m in length. 5. Rechargeable battery operated. 6. Battery charger characteristics: Amperage: _____; Voltage: _____. 7. Capable of operating continuously in ambient temperature of 10 to 40°C, and relative humidity of RH: 30% to 95%. [Bilirubinometers must use a constant supply of electricity to operate, so energy efficiency should be one of the main considerations when choosing an environmentally preferred system. Some suppliers offer light-emitting diode (LED) displays with their systems, which use less energy than liquid crystal displays (LCDs)].
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Hard and splash-proof case to be supplied
26	Sterilization process for accessories (if relevant)	The case is to be cleanable with alcohol or chlorine wipes
27	Consumables / reagents (if relevant)	Disposable Cuvettes
28	Spare parts (if relevant)	Two sets of spare/replaceable fuses and/or batteries, five replacement rolls of printer paper, reagents and capillary tubes sufficient for 100 tests. Spare light source.
29	Other components (if relevant)	Capillary tubes, haemofluorometric reagents (e.g., aqueous cyanide salt with stabilizers, if applicable).
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	1. Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. 2. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover.
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
38	User care(if relevant)	
WARRANTY AND MAINTENANCE		
39	Warranty	Two year warranty should be provided by the supplier.
40	Maintenance tasks	Advanced maintenance tasks required shall be documented.
41	Type of service contract	N/A

42	Spare parts availability post-warranty	N/A
43	Software / Hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	1. User, technical and maintenance manuals to be supplied in (**** language). 2. List to be provided of equipment and procedures required for local calibration and routine maintenance. 3. List to be provided of important spares and accessories with their part numbers and cost.
DECOMMISSIONING		
45	Estimated Life Span	8 years
SAFETY AND STANDARDS		
46	Risk Classification	Class A (GHTF Rule 4); Class II (USA); Class I (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	FDA approval (USA); CE mark (EU)
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU). ISO 14971:2007 Medical devices -- Application of risk management to medical devices. IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
49	Reginal / Local Standards	N/A
50	Regulations	**US regulations** 21 CFR part 820 21CFR section 862.11106 diazo colorimetry, bilirubin **EU regulations** Council Directive 93/42/EEC Directive 93/68/EEC (CE Marking) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC **Japan regulations** MHLW Ordinance No.169 (Japan) 35475000 Bilirubinometry analyser (Japan)

3. Bililight Preventative Maintenance

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Bililight Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

EQUIPMENT

Bililight Preventative Maintenance

Preventive Maintenance List for Bililight

1. Check for signs of physical damage or abuse
2. Check for evidence of fluid spills
3. Check AC plug/cord/receptacle
4. Check strain relief at both ends of cord
5. Check controls/switches
6. Check power-on sequence
7. Check for unusual noise or vibration
8. Clean interior/exterior as required
9. Test all audible & visual alarms and indicators
10. Measure chassis ground resistance
11. Measure chassis leakage current
12. Clean air filter
13. Electrical safety
14. Measure light output

Cooper, Justin and Alex Dahinten for EWH. "Bililight Preventative Maintenance." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Preventative Maintenance Table for Lights

User Care of Medical Equipment – First line maintenance for end users

User Care Checklist – Lamps

Daily	
Cleaning	✓ Wipe dust off exterior and cover equipment after checks
Visual checks	✓ Check all fittings and accessories are mounted correctly ✓ Check there are no cracks in glass / covers or liquid spillages
Function checks	✓ If in use that day, run a brief function check before clinic

Weekly	
Cleaning	✓ Unplug, clean outside with damp cloth and dry off ✓ Clean any filters, covers and battery compartment ✓ Remove dirt from wheels/any moving part
Visual checks	✓ Check all screws and parts are fitted tightly ✓ Check mains plug screws are tight ✓ Check mains cable has no bare wire and is not damaged
Function checks	✓ Check all switches operate correctly ✓ Remove or charge batteries if out of use

Every six months
Biomedical Technician check required

4. Troubleshooting and Repair of Bililights

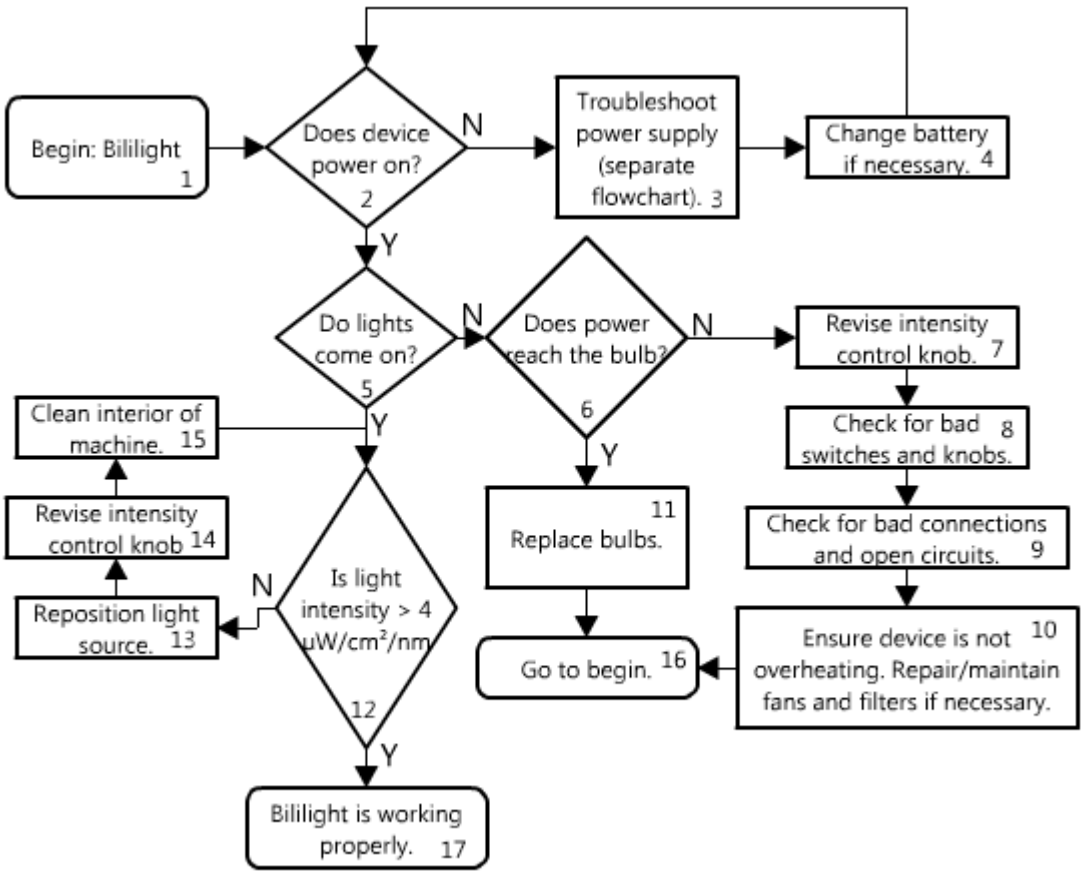
Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Bililight Troubleshooting Flowchart From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Bililight Troubleshooting Flowchart

Troubleshooting Flowchart for Bililight



#	Text Box	Explanation or Comment
1	Begin: Bililight	Start the diagnostic process for a work order on a bililight.
2	Does device power on?	Displays, lights, and sounds are all indicators that the device has turned on.
3	Troubleshoot power supply (separate flowchart).	Most bililights have an AC-DC power supply.
4	Change battery if necessary.	Some bililights may have a batterty.
5	Do lights come on?	Do the blue lights illuminate when they are switched on?
6	Does power reach bulb?	Does the appropriate voltage reach the input for the bulb?
7	Revise intensity control knob.	Make sure any intensity control knob is turned up to allow the lights to illuminate.
8	Check for bad switches and knobs.	Review switches and potentiometers for faults.
9	Check for bad connections and open circuits	Open circuits, bad connections, and bad wires can prevent the lights from illuminating.

Cooper, Justin and Alex Dahinten for EWH. "Bililight Repair and Troubleshooting." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

10	Ensure device is not overheating. Repair/maintain fans and filters if necessary.	Some bililights have a safety mechanism that turns the lights off when the device overheats. If this is the case, try allowing the device to cool before attempting to turn the lights on again. If this was the problem, consider ways to improve ventilation.
11	Replace bulbs.	If the appropriate voltage reaches the bulbs and they do not illuminate, the bulbs must be replaced.
12	Is light intensity > 4μW/cm^2/nm	Measure the light output at patient-level. 4μW/cm^2/nm is the minimum output for a bililight, though many have outputs higher than this (e.g. 15μW/cm^2/nm)
13	Reposition light source.	If the intensity is too low, the light source may be position too far from the patient.
14	Revise intensity control knob.	The light intensity might be increased by manipulating the intensity control knob.
15	Clean interior of machine.	If the interior of the machine or the bulbs are dirty, it might obstruct the light source or cause overheating of the device.
16	Go to begin.	Start the diagnostic process again to see if the corrective measures have solved the problem.
17	Bililight is working properly.	The light intensity is above the minimum, and the device can be used with patients.

Lights Troubleshooting Table

User Care of Medical Equipment – First line maintenance for end users

Troubleshooting – Lamps

	Fault	Possible Cause	Solution
1.	No light or 'power on' visible	No power at mains socket	Check power switch is on. Replace fuse with correct rating of voltage and current if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
		Dead battery	Charge or replace batteries
		Blown bulb	Replace bulb with correct voltage and wattage
		Battery leakage	Remove batteries (if accessible), clean battery terminals and replace with new battery
		Electrical cable fault	Try cable on another piece of equipment. Contact electrician for repair if required.
		Internal wiring fault	Refer to electrician
2.	Fuse / bulb keeps blowing	Fuse or bulb is wrong rating	Replace with correct rating
		Power supply or cable fault	Refer to electrician
3.	Light cannot be made bright enough	Dirt on lens or tube	Clean area with dry, clean cotton
		Poor power supply	Check power line or replace batteries
		Wrong bulb rating	Check bulb rating is correct
		Control malfunction	Refer to electrician
4.	Electrical shocks	Wiring fault	Refer to electrician

5. Resources for More Information about Bililights

Featured in this Section:

Wikibooks Contributors. “17 Pregnancy and Birth.” *Human Physiology*. Wikibooks, 2006.

Resources for More Information:

Internal Resources at library.ewh.org: For more information about bilirubin and infants, please see this resource in the BMET Library!

1. Wikibooks Contributors. “17 Pregnancy and Birth.” *Human Physiology*. Wikibooks, 2006. See specifically the section about “Blood Conditions” on page 340.

Bililights Bibliography:

Cooper, Justin and Alex Dahinten for EWH. "Bililight Maintenance." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

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WHO. "Phototherapy units, hyperbilirubinemia." From the page: "Hospital medical equipment: Data Sheets 2012." *WHO*. Retrieved from: http://www.who.int/medical_devices/innovation/core_equipment/en/index1.html

WHO. "Bilirubinometer." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

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Wikipedia. "Neonatal Jaundice." *Wikipedia.* Retrieved from: https://en.wikipedia.org/wiki/Neonatal_jaundice