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PREVENTION OF MEDICATION ERRORS IN NEONATES

By Gautham Suresh, MD; Stuart Levine, Pharm D; and Michelle Mandrack, RN, BSN

INTRODUCTION AND DEFINITIONS

In recent years it has become widely recognized that medical errors are a significant cause of morbidity and mortality in both hospitalized and ambulatory patients [1]. A medical error is defined as "Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" [1].

Among medical errors, those related to the use of medications – medication errors – are a particularly important category because the high frequency of medication use in patient care makes such errors common and serious. Because of the importance of medication errors, several of the National Patient Safety Goals put forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) address the prevention of medication errors [2]. Neonatal intensive care unit (NICU) patients are vulnerable to medication errors, as highlighted by the recent press and media reports of medication errors in one NICU, where six preterm infants inadvertently received overdoses of heparin, and three of these infants died [3]. In this article we discuss the epidemiology, pathogenesis, types and methods of prevention of medication errors. We will focus particularly on how neonatologists, neonatal nurse practitioners, and other prescribers who care for newborn infants can help to

decrease the risk of medication errors. Although neonatologists do not usually dispense or administer medications, because they are in a position to promote system-wide improvements, they can profoundly impact medication safety in their units.

Medication errors can result in four types of consequences. The patient may:

- (1) Not receive an intended drug,
- (2) Receive the wrong dose – higher or lower – of the drug,
- (3) Receive a drug that was not intended for him or her, or
- (4) Attain undesirable levels of the drug in the body.

However, the actual degree of harm to the patient can vary. The patient might not be harmed even if exposed to a medication error, or may suffer varying degrees of harm, including serious injury or death. "Near-misses" are errors in which the patient escapes harm in spite of being exposed to the error. Medication errors should not be confused with adverse drug events (ADE). An ADE is an injury resulting from medical intervention related to a drug, which can be from preventable or non-preventable causes. Preventable ADEs are those resulting from a medication error. Non-preventable ADEs are those resulting from the adverse effects or toxic reactions related to the inherent pharmacologic properties of the drug [1]. Not all medication errors result in ADE's and not all ADE's are the result of medication errors.

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Children, and especially neonates, may be at higher risk of medication errors than adults. Several studies have described the frequency and types of medication errors in neonates. Medication errors across these studies were reported to occur 5 to 57 times per 1000 medication orders, and in 15 – 91% of hospital admissions [4,5,6,7]. A particularly important sub-category of administration errors is that of errors in programming infusion pumps. Such errors result in overdosing or under-dosing of continuous medication infusions such as morphine and dopamine.

PATHOGENESIS OF MEDICATION ERRORS

The Institute for Safe Medication Practices (ISMP) has identified ten key system elements that have the greatest influence on medication use. These elements are: patient information, drug information, communication, labeling, storage, use of devices, environmental factors, staff education and competency, patient education, and quality and risk management processes [8]. Medication errors occur due to breakdowns at vulnerable points in these key elements.

A common tendency is to place blame for an error on the physician, nurse or other health professional involved in the event. However, human performance is never perfect, and most humans will make errors in a certain percentage of all activities they undertake. Most medical errors occur not from the carelessness or negligence of individuals, but from a combination of human fallibility and the presence of error-facilitating working conditions that are common in most systems of care [9]. Such error-facilitating conditions are called “latent conditions” and include factors such as excessive patient-physician/nurse ratios; excessively long work hours leading to health professional fatigue; improper design or lack of equipment such as infusion pumps; poor communication among health professionals; frequent distractions and interruptions; non-standard practices; poor formulary management; lack of well-designed automation; and poor physical work environment (for example, poor lighting). In addition, health professionals are usually not trained to think in a “safety-minded” fashion, so they are often not aware of the safety hazards in their work setting, and of their own risks of error commission. Finally, and most importantly, a lack of a culture of safety in the organization contributes significantly towards the occurrence of errors. In organizations that have an optimal culture of safety, errors and near-misses are openly discussed without blaming individuals, with the intention of eliminating system-based causes of error.

PREVENTION OF MEDICATION ERRORS

The following is a compilation of recommendations from multiple sources [2,10,11,12], organized according to the ten key system elements listed above. Admittedly, these recommendations have not been tested in randomized controlled trials – they are based on lower levels of evidence, such as expert opinion and reasoning based on knowledge of human psychology and behavior.

Patient Information:

Identification:

Failure to identify the correct patient is a common type of medical error and occurred in 11% of error reports in one study [13]. At any given time, two or more patients in a neonatal unit can have the same name or similar-sounding names, thus creating an opportunity for mis-identification [14]. Accurate identification of the patient is an important component of all steps of the medication use process, from prescription to monitoring. Two identifiers, such as the patient's name and the medical record number, should be used to confirm the patient's identification. The patient's bed number, the patient's room number, or the patient's location within a room should not be used to confirm the patient's identity [2]. Each neonatal patient should have an identification band on one of the limbs, with his or her name, date of birth, medical record number and other information clearly marked on it. Such bands should not be removed from the patient's body. If they need to be removed for placement of intravenous catheters or blood sampling, they should immediately be moved to a different limb. Bar-coding at the point of medication administration is increasingly being recommended and used, and provides a final identity check before medication administration to the patient.

Weight:

It is important to have the patient's weight available and immediately accessible. This allows for an independent double check of doses by nurses and pharmacists. Even if the exact weight is not known initially, estimated weight should be included with the order.

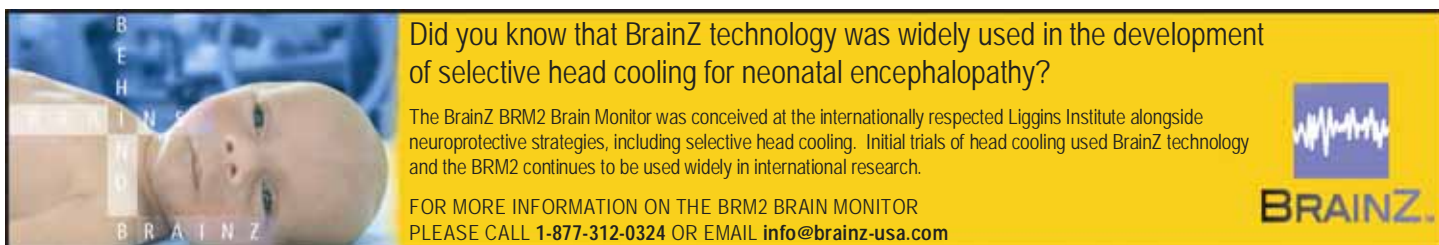
Check for Contraindications, Including Allergies:

Each patient should be assessed for the presence of contraindications to the medication that is going to be prescribed. For example, neonates with hyperbilirubinemia should not receive ceftriaxone. Sometimes such contraindications arise from potential drug-drug interactions with other drugs the patient is already receiving. Allergies are rare in neonates, but the existence of other types of contraindications for the medication to be prescribed should be clearly documented in the patient's chart and should be marked prominently on the outside of the patient's chart.

Drug Information

Drug References:

Current and appropriate drug reference information should be available and easily accessible on every neonatal unit, so that nurses and pharmacists taking care of these patients can review and verify medication orders. The same references should be available in the pharmacy as a consistent source of drug information.



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High-alert Drugs:

As part of the organization's medication error reduction strategies, a list of high-alert drugs should be identified that is specific for each patient care unit. Drugs on this list should require additional checks on the part of house staff, nurses, and pharmacists. For example, when high-alert medication infusion is to be used, two persons should be required to independently check the calculations, the preparation of the medication, and the infusion pump settings. This verification and checking process should be identified for each drug established as a high-alert medication.

Drug Formulary:

To decrease the risk of error, only those medications in the formulary should be prescribed, and the formulary should be routinely reviewed. As part of the formulary review, clinicians and pharmacists should reduce the number of therapeutic duplications in a therapeutic class, remove medications no longer required, and review the inventory and par levels of floor stock on the patient care unit. Neonatologists' influence on what is stored on the unit and the par levels can have a direct impact on the potential for errors. For example, removal of concentrated potassium chloride solution from patient care units, as recommended by JCAHO, substantially reduces the risk of inadvertent intravenous potassium overdoses [2].

Avoidance of Unnecessary Medication Use:

A common medication error is the use of a medication when none is necessary. Medications should be used only when necessary. Prior to prescribing a medication, each prescriber should ask the question: "Is this drug really necessary for this patient?"

Computerized Physician Order Entry Systems:

Such systems show great promise in the prevention of medication errors but are expensive to implement and maintain [15]. They can also lead to a different set of errors [16,17]. Many of the types of errors that occur relate to the quality of the implementation. Since they are not widely available, we will focus in this article on handwritten prescriptions.

Clinical Pharmacy Services:

One of the most effective tools in reducing medication errors is the addition of a clinical pharmacist to the NICU team to routinely round in the unit. The inclusion of pharmacists in daily patient rounds has the potential to reduce medication errors, by as much as 81% [18,19]. Such pharmacists also serve as a ready source of drug information to the patient-care team and can provide valuable advice about drug selection, the presence of contraindications, drug doses, administration intervals and the need for modification of drug doses and intervals based on monitored levels.

With the use of medications that require monitoring of serum or other levels, reminder systems should be established that trigger

the ordering of such levels at the appropriate times. Monitoring may also be required for biochemical or physiological effects of specific drugs (e.g., electrolyte monitoring with diuretic therapy). The presence of a clinical pharmacist in rounds can ensure that patient rounds include a discussion of the monitoring of medication levels and medication effects.

Standardization:

Each institution should standardize weight measurement in children and neonates to metric units of measure – grams and kilograms should be used, and not pounds and ounces. Prescribers should double check the accuracy of the patient's weight they are using for dosage calculation, and should use a calculator to perform the calculation. The weight-based dosage guidelines should be checked in a pediatric dosage handbook and not retrieved from memory, especially for drugs used infrequently.

It is also important to establish standardized concentrations of critical care drugs and other neonatal continuous IV medication infusions to avoid errors in calculation and preparation. JCAHO recommends that organizations should standardize and limit the number of drug concentrations available, and eliminate the use of the 'rule-of-six' in preparing medication infusions [2]. The use of corresponding weight-based charts with associated dosages in micrograms per kilogram per minute can also be a beneficial strategy to prevent error-prone calculations and the use of the wrong diluent or volume.

Clinicians should introspect about the "style" of their practice versus their colleagues'. Do they use different medications at different doses and frequencies than their colleagues? The more the variation, the more the confusion, and the more the likelihood of errors occurring. Groups of clinicians working who cross-cover patients should try to reach consensus on how they will manage similar patients, in order to decrease variation.

Communication

Every prescription should include the following minimum information: patient's name, medical record number, weight (in metric units), drug name, dose, dosage form, route of administration, instructions for use, indication for the drug, prescriber's signature, legible prescriber's name, pager or telephone number, and date and time of prescription. As mentioned above, the presence of drug allergies, a history of other adverse drug reactions, and the presence of known contraindications should be documented prominently in the patient's chart, so that prescribers have easy access to this information. In addition to the prescribed dose, the dose used for calculation (for example, "ampicillin 300 milligrams/kg/day") should be included, to enable the nurse and the pharmacist to cross check the dosage calculations. Vague instructions for administration of the drug, such as "take as directed" or "prn" should be avoided. If a medication is prescribed to be given "prn" (as needed), the indications for when the medi-



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cation should be administered and the minimum interval between doses should be clearly stated in the prescription.

Generic names should be used for medications, rather than brand names, except when a commercially formulated premixed combination of multiple drugs is being prescribed, such as Aldactazide, a commercial combination of spironolactone and hydrochlorothiazide. The name of the medication should be written legibly and prescribers with poor handwriting should write the medication name in block letters. If the drug name is very similar to that of another medication, part of the name can be capitalized, to avoid confusion, e.g. writing "doBUTamine" instead of "dobutamine" will help avoid confusion with "dopamine." This is known as "tall man" lettering. Drug names should not be abbreviated (e.g., if a prescriber writes "MS" to indicate morphine sulfate, it can lead to the mistaken administration of magnesium sulfate). In the case of medications where different salt forms have different effects (e.g., caffeine citrate versus caffeine base), the exact salt formulation to be dispensed should be specified.

The amount of the drug to be administered should be written legibly, without any overwriting or alteration of numbers. If the amount of the prescribed drug is less than one, a zero should always be written in front of the decimal point (e.g., "0.4 milligrams" and not ".4 milligrams" to avoid a ten-fold overdose from the decimal point being overlooked). If the amount is a whole number, a decimal point should not be used. An unnecessary decimal point followed by a zero should never be used (e.g., "18 milligrams" should be written, not "18.0 milligrams" to avoid a ten-fold overdose from an overlooked decimal point). Unnecessary precision in the prescribed dose should be avoided by rounding the numbers (e.g., "Ampicillin 253.58 milligrams" can easily be changed to "Ampicillin 250 milligrams").

Dosage units should be spelled out instead of using abbreviations (e.g., "micrograms" instead of "µg"). For medications whose dose is expressed in units (heparin, insulin) or international units (Vitamin A), the complete word "units" should be used instead of the letters "U" or "IU". Dosages should always be ordered in metric units such as milligrams or milliliters, not in tablets, capsules, vials or ampoules.

The use of abbreviations when prescribing medications is fraught with error. A good list of error-prone abbreviations, symbols and dose designations to avoid is found on the website of the Institute for Safe Medication Practices [20].

Verbal or oral orders should be avoided whenever possible. If a verbal order must be given, the name of the drug should be spelled out, the amount should be stated in words as well as numbers (e.g., saying "fifty, that is, five-zero" avoids confusion with "fifteen") and the person receiving the verbal order should read back the order to the prescriber, just like a waiter in a restaurant reads back the meal order to the customer.

Every institution should use standardized order sheets for ordering medications. The use of order sheets with pre-printed fields for the various components of the medica-



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tion prescription has been shown to reduce errors [21,22]. Standardized order sets should be used when possible. For example, having a printed sheet with all the orders commonly required when a patient is admitted can help reduce omission errors at admission.

The quality of order transmittal to the pharmacy should be enhanced by scanning the original copy of the order and not the NCR copy that may contain stray marks. Consider eliminating the NCR order form copies to facilitate this process.

Drug Labeling, Packaging, and Nomenclature

While labeling of medications may not appear to be a concern of the clinician, medications are sometimes administered directly by clinicians. Whether it is the clinician that takes the medication from unit stock, or the nurse who hands the medication to the clinician, the potential for medications that look-alike or sound-alike to be mistaken for each other is a major concern, and one that is emphasized by JCAHO as well [2]. For example, during delivery room resuscitation of a neonate, when a clinician is handed an unlabelled syringe or vial to administer to the patient, there is significant risk of administering the wrong medication, or the wrong dose of a medication. Every syringe or vial containing medications, flushes, intravenous fluids, or parenteral nutrition fluid or its components should be clearly and legibly labeled.

Many labels have the concentration as the focus of the label, which can lead to errors, especially for medications that need to be prepared on the clinical unit. Therefore, the label should stress the patient-specific dose rather than the concentration. Guidelines for labels can be found at the ISMP website at www.ismp.org under Tools. Information from the *ISMP Medication Safety Alerts!* and other literature can help identify drugs with error-prone, ambiguous, or look-alike drug names, packages, and labeling. Specific, bold auxiliary warning labels should be used for look- and sound-alike products in the pharmacy and on the nursing units to facilitate accurate stocking and retrieval of drugs. The use of tall man lettering as described above (a combination of upper and lower case characters) should be used to differentiate look-alike drug names (*hydrOXYzine* vs. *hydrALAZINE*, *hePARin* vs. *HESpan*, *CISplatin* vs. *CARBOplatin*, *DOBUTamine* vs. *DOPamine*, etc.) on storage bins/shelves and on computer screens.

Drug Storage and Stock

As a rule, the hospital pharmacy should provide all neonatal medications in patient-specific doses. However, procedures should be developed for the preparation of IV medications in emergent situations. Implementing formalized preparation procedures will help to minimize variation and resulting dosing errors.

Medications are not only stored in the pharmacy but also on neonatal units, either as stock in a medication area or in an automated dispensing cabinet. Neonatologists and nurse practitioners should take an interest in, and influence the variety and quantities

of medications stocked in the unit. Examples of questions they might ask are – “Are these medications that we commonly use? Do we need to have them emergently? Is there time for the pharmacist to review those medications prior to administration? Do we routinely stock neuromuscular blockers? How many different agents are stocked? Are all of those agents necessary? Are there medications that require dilution or extensive calculations by the nurse, or house staff, in preparing the patient-specific dose?” Ideally, drugs that require extensive or complicated calculations or dilutions should only be prepared by a pharmacy where safety systems such as a double check and calculation verification are in place.

Medications that are stored and retrieved directly from the patient care areas often escape review by the pharmacist before administration. When individual drugs are available in large quantities in the clinical area, nurses and house staff are at increased risk of preparing a significant overdose simply because of the availability of the medication. Therefore, if a medication is stored on the unit, the quantity available should be limited.

Devices

Every neonatal unit should have a variety of oral syringes clearly and prominently labeled, “For Oral Use Only,” and require their use for the administration of small volume oral/enteral medications. In addition, nurses and house staff should be educated about the danger of inadvertent parenteral administration of an oral liquid medication from syringes intended for IV use. Many of these syringes readily fit parenteral line ports. There have been many catastrophes when substances intended for oral use, such as enteral medications, suspensions, or breast milk, and even surfactant, have been inadvertently given intravenously (i.e., wrong route errors) [13,23,24,25].

When infusing medications continuously using infusion pumps, errors often occur due to misprogramming of the infusion rate, the wrong infusion tubing being placed in the infusion pump channel, or the infusion rates of two concurrent infusions being exchanged for each other. For example, when parenteral nutrition is being administered, a common error is the infusion of the glucose-amino-acid solution at the rate of the intravenous lipid and vice-versa, resulting in an overdose of intravenous lipid [13]. For high-alert medications, two nurses should ideally check the infusion rates.

Clinicians should be part of the effort to standardize the manufacturer, model, and version of infusion devices on the unit. Many times there are numerous pumps from the same manufacturer but they are different models or have different versions of software. This makes it difficult to provide training for staff and this variation leads to confusion and errors. Smart pumps can provide another layer of safety if the libraries are developed and routinely utilized by staff [26]. If the unit is moving toward the use of smart pumps, clinicians should participate the discussions and decisions.

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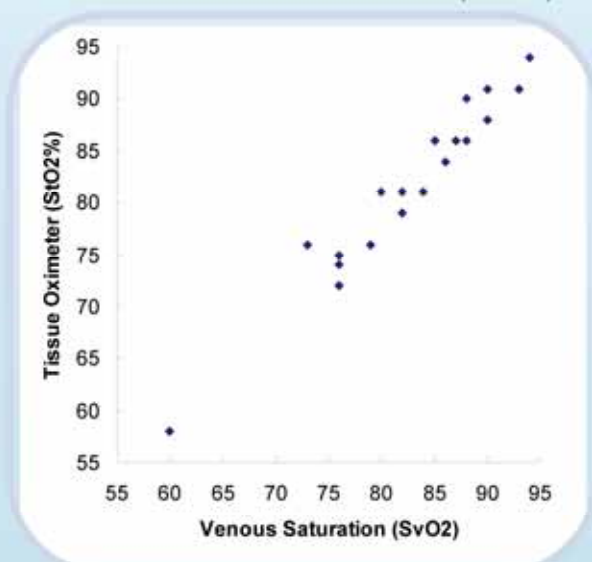
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Environment and Workflow

Every neonatal unit should provide a dedicated space to prescribe and prepare medications with a minimum of distraction. Many organizations, recognizing the risk of error when clinicians are writing/entering orders in settings prone to interruptions, noise, monitor alarms, and phones have designated a "sterile cockpit" area for physicians to enter orders, document clinical assessments, and dictate charts.

Poor lighting is another environmental challenge and is a particular problem in neonatal units. While lighting is low to reduce stimulation of the neonate, and for developmental care, each unit requires locations with sufficient light to read labels or medication administration records (MARs). Simple methods such as making flashlights easily available to staff, or a gooseneck light over a bedside table or cart may be all that are required. Currently many neonatal units are being redesigned and new ones being built. Provision of work areas with sufficient lighting is an essential part of such NICU design or redesign.

Staff Education and Competency

Formal mechanisms are needed to regularly assess and improve clinician competence in the processes of medication selection, prescription, administration and monitoring for neonatal patients. Several studies have shown that the mathematical skills of doctors and nurses are often deficient [27,28]. In addition, insufficient knowledge about a medication is a leading cause of drug errors [29]. Designated resources should be available for maintaining clinician competence in neonatal and pediatric pharmacology.

Health professional education and training is focused primarily on adults. Generally, only a small percentage of overall health professional training is allocated to training in pediatrics, most often during residencies and fellowships in organizations that specialize

in neonatal and pediatric care [29]. This can create particular risks for medication safety when professionals not trained in pediatrics, or those who do not routinely take care of neonatal patients, are scheduled to work in the neonatal intensive care unit. Examples are residents from Anesthesiology or Medicine-Pediatrics departments, and nurses from other pediatric units or from a central hospital pool who are scheduled to work in the neonatal intensive care unit. Special attention should be paid to training and orienting such staff during their neonatal rotations.

Patient Education

When medications are prescribed to neonates at hospital discharge, it is essential to educate the parents about the indications for each medication, the method of administration, the route and frequency of administration, the total duration of treatment and the possible adverse effects. This information should be also be provided in written form at the appropriate reading level. If applicable, the parents should be given oral syringes clearly marked with the dosage volume and should demonstrate their ability to accurately measure and administer discharge medications.

Each medication dispensed for use at home should be clearly labeled, with printed instructions. Such instructions are especially important if twins or other multiple births are being discharged with medications, in order to avoid errors in medication administration. Parents should also be provided with the written name and telephone number of a physician, pharmacist or nurse to call with questions or problems if any arise. For patients with limited English proficiency, qualified interpreters should be used for parental education, and written material should be provided in the parents' preferred language.

Quality Process and Risk Management:

The 'safety culture' of the unit is key to incorporating error prevention into everyday work. Leaders of neonatal units should strive



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to create a safe, just culture in the work environment where staff feel comfortable about reporting medication errors, or potential medication errors. For error reporting to be successful, individuals who report errors should feel that they are contributing to patient safety and will not be punished or blamed for errors [30]. When errors occur in a unit, the physician, nurse, or other health professional who was involved in the occurrence or discovery of the error should report the error, either using a paper-based form or a computer-based reporting system. Details of how the error occurred, why it occurred, the amount of harm resulting to the patient and details of the medication involved should be collected. Periodically, all reported errors should be collated and analyzed for patterns by the nursing, pharmacy and physician leaders of the unit. If serious harm results to a patient from an error, a root cause analysis of the incident should be performed [31]. Such processes allow prioritization of interventions that can target common and serious errors, and lead to increased learning about errors and their prevention.

CONCLUSION

Medication errors are a common and serious problem in neonatal intensive care units and focused efforts are required to eliminate harm to patients from preventable adverse drug events. A variety of prevention strategies have been proposed by experts, and these can be grouped under ten key system elements: patient information, drug information, communication, labeling, storage, use of devices, environmental factors, staff education and competency, patient education, and quality and risk management processes. Neonatologists, neonatal nurse practitioners, pharmacists, nurses and other neonatal health professionals should work together to improve the safety culture of their units, implement recommended practices, and to improve the safety of medication use in their units.

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Medical News, Products and Information

Phototherapy for Neonatal Jaundice Associated with Increased Risk of Skin Moles in Childhood Libraries

Children who received light therapy (phototherapy) for jaundice as infants appear to have an increased risk of developing skin moles in childhood, according to a report in the December issue of Archives of Dermatology, one of the JAMA/Archives journals. Some types of moles are risk factors for developing the skin cancer melanoma.

Jaundice or hyperbilirubinemia occurs when bilirubin, a yellow pigment created as a by-product of the normal breakdown of red blood cells, cannot yet be processed by a newborn's liver and builds up in the blood, turning the skin, whites of the eyes and mucous membranes yellow. The condition affects between 45% and 60% of healthy babies and as many as 80% of infants born prematurely, according to background information in the article. During phototherapy, the treatment of choice for jaundice, babies are placed under blue lights (bili lights) that convert the bilirubin into compounds that can be eliminated from the body. Studies have been performed to assess the safety of this therapy, but many have not focused on its effects on the skin, the authors write.

Emmanuelle Matchard, MD, Bichat-Claude Bernard Hospital, Saint-Antoine Hospital, Assistance Publique-Hôpitaux de Paris, and colleagues assessed the presence of melanocytic nevi (moles) in 58 French children who were 8 or 9 years old at the time of the study. Eighteen children had phototherapy as newborns; 40 who were the same age but did not have phototherapy were recruited from a public school and served as controls. All the children and their parents were interviewed about the use of phototherapy, history of sun exposure and sunscreen use. A dermatologist performed physical examinations on the children and

recorded their skin color, eye color, hair color, skin type and the number and size of moles.

Thirty-seven children (63%) had moles that were 2 millimeters or larger, and there was an average of 2.09 moles per child. Those who were exposed to phototherapy had significantly more moles of this size than those who did not—an average of 3.5 vs. 1.45 per child. When the analysis was limited to moles between 2 millimeters and 5 millimeters, the association was stronger. "Lentigo simplex [moles smaller than 2 millimeters in diameter] may represent more recent nevi, whereas those nevi due to early events should be larger," the authors write. "Nevi larger than 5 millimeters probably are congenital nevi and are most probably associated with genetic predisposition." These associations did not change when other risk factors for the frequency of moles, including skin type and light hair, were considered. Sun exposure, particularly during vacations, was also associated with the number of moles of all sizes, and light hair color was correlated with the number of moles smaller than 2 millimeters.

The study did not examine whether phototherapy increases the risk for melanoma in adults, and it is possible that the small difference in the number of moles between the two groups would not change their risk of developing cancer. However, further study could help illuminate the association. "Higher numbers of acquired benign nevi are associated with increased risk of melanoma," they conclude. "A detailed evaluation of the factors responsible for the development of nevi in children would be useful to identify high-risk groups to be targeted for prevention. The link between melanoma and phototherapy should be the focus of such a study."

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