Human placentophagy: a review

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Placentophagy or placentophagia, the postpartum ingestion of the placenta, is widespread among mammals; however, no contemporary human culture incorporates eating placenta postpartum as part of its traditions. At present, there is an increasing interest in placentophagy among postpartum women, especially in the United States. The placenta can be eaten raw, cooked, roasted, dehydrated, or encapsulated or through smoothies and tinctures. The most frequently used preparation appears to be placenta encapsulation after steaming and dehydration. Numerous companies offer to prepare the placenta for consumption, although the evidence for positive effects of human placentophagy is anecdotal and limited to self-reported surveys. Without any scientific evidence, individuals promoting placentophagy, especially in the form of placenta encapsulation, claim that it is associated with certain physical and psychosocial benefits. We found that there is no scientific evidence of any clinical benefit of placentophagy among humans, and no placental nutrients and hormones are retained in sufficient amounts after placenta encapsulation to be potentially helpful to the mother postpartum. In contrast to the belief of clinical benefits associated with human placentophagy, the Centers for Disease Control and Prevention recently issued a warning due to a case in which a newborn infant developed recurrent neonatal group B *Streptococcus* sepsis after the mother ingested contaminated placenta capsules containing *Streptococcus agalactiae*. The Centers for Disease Control and Prevention recommended that the intake of placenta capsules should be avoided owing to inadequate eradication of infectious pathogens during the encapsulation process. Therefore, in response to a woman who expresses an interest in placentophagy, physicians should inform her about the reported risks and the absence of clinical benefits associated with the ingestion. In addition, clinicians should inquire regarding a history of placenta ingestion in cases of postpartum maternal or neonatal infections such as group B *Streptococcus* sepsis. In conclusion, there is no professional responsibility on clinicians to offer placentophagy to pregnant women. Moreover, because placentophagy is potentially harmful with no documented benefit, counseling women should be directive: physicians should discourage this practice. Health care organizations should develop clear clinical guidelines to implement a scientific and professional approach to human placentophagy.

Key words: placenta, placenta consumption, placenta encapsulation, placentophagia, placentophagy

Over the last few decades, many cultures have been fascinated by the placenta owing to its mysterious and essential role in fetal development and maternal health.[1,2] Most obstetricians have considered the placenta for the longest time as an afterthought or an afterbirth, especially in comparison with the mother and the newborn infant.[3]

In the United States, the growing interest in natural childbirth appears to be connected to a growing interest in placentophagy, the practice of consuming the placenta after birth.[4-6] During the last 10 years, the number of Google searches for placenta encapsulation, the most common form of this practice, has continued to rise (Figure 1).[7]

Most mammals routinely ingest their placenta,[8,9] while there is no contemporary human culture that incorporates placentophagy as part of its traditions.[10] In 1917, Hammett and McNeile[11] published one of the earliest available papers reporting an increase of protein and lactose content in the breast milk of women who ingested their desiccated placenta during the first few days after delivery.

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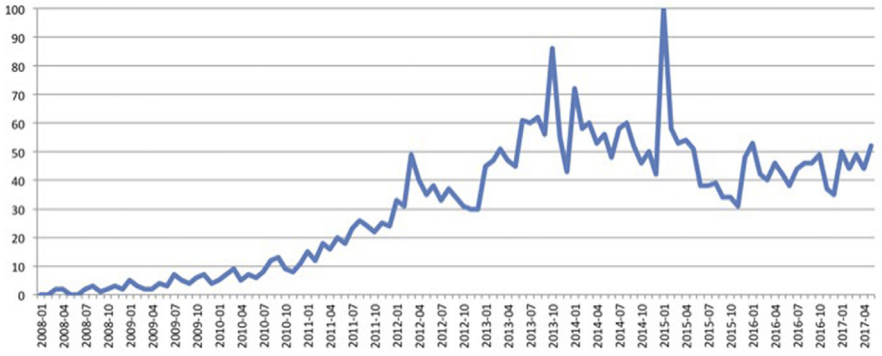
Anthropological theories suggest that the emerging use of fire by the *Homo erectus* almost 2 million years ago could have resulted in the disappearance of routine placentophagy in humans because pregnant women needed to be protected from burning toxins that could have accumulated, harmed the mother, and, perhaps, the newborn infant.[12] Several hypotheses were offered as rationales behind the ingestion of placenta by most mammals, demonstrating a relationship between placentophagy and some particular behavioral and physiological outcomes.[10,13]

It is known that the placenta contains high levels of prostaglandins, which stimulate the involution of the uterus.[14] The small amounts of oxytocin in the placenta cause the smooth muscles around the mammary cells to contract and eject milk.[15] Rats who ingested their placentae were shown to have increased levels of serum prolactin and lower levels of progesterone than the corresponding levels of those who did not do so.[16]

FIGURE 1
Interest over time (2008–2017) for the term "placenta encapsulation"



Interest over time (2008–2017) for the term "placenta encapsulation" according to Google Trends (numbers represent search interest relative to the highest point on the chart for the given time. A value of 100 is the peak popularity for the term. A value of 50 means that the term is half as popular. Likewise a score of 0 means the term was less than 1% as popular as the peak.[7])

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Despite this finding, placentophagy seems to induce an analgesic effect in rodents, increasing the pain threshold without inhibiting the ability to care for the offspring.[17] Preliminary research points to several other possible effects in rats, including the restoration of normative gut activity and the blocking of pseudopregnancy.[18,19]

There is a school of thought that suggests that placentophagy naturally occurred to hide any trace of childbirth from predators in the wild.[20] It should be noted that the ingestion of human placenta by rats did not yield any hormonal effects, thus demonstrating that the induced animal effects may be species specific and should not be generalized to humans.[16]

To date, there is no scientific evidence for any clinical benefit of human placentophagy. Positive influences on mood, iron status, lactation, and general energy that have been claimed by the supporters of placentophagy have never been proven in clinical studies. This is of particular importance in the light of a recently conducted survey on placentophagy reporting that 53.6% of obstetricians and gynecologists believed they were uninformed about the risks and benefits of this practice and that 60% of them were unsure whether they should be in favor of placentophagy.[21]

This experience might reflect the taboo nature of this topic arising from the fact that humans do not eat the placenta.[22] Very few papers have been published in peer-reviewed scientific and clinical journals that would help obstetrician-gynecologists counsel women on placentophagy.[23,24]

In the modern Western society, ingesting the placenta is against the beliefs of the majority of individuals. Nevertheless, there is increased interest in this practice, and health care professionals should be prepared to respond to expressions of interest in placentophagy in a uniform and professionally responsible manner. This review aims to provide scientifically and clinically relevant considerations, including the risks and benefits of placentophagy as well as to identify their implications for a professionally responsible approach to counseling women who may be interested in this practice.

The placenta: a complex organ

The placenta is a highly complex organ, derived from the trophoblasts, which develops from the same blastocyst as the embryo. The decidua (basalis, parietalis, and capsularis) develops from the maternal uterine tissue. Trophoblast cells invade the endometrial tissue and vascular system to form the chorionic villi and remaining placental components. These cells are originally derived from the embryo.[25-27]

The importance of placentation is demonstrated by errors that occur in this vulnerable phase, which are associated with some of the major challenges in obstetrics, such as preeclampsia, intrauterine growth restriction, fetal demise, preterm labor, preterm premature rupture of membranes, spontaneous abortion, and abruptio placentae.[28-31]

During pregnancy, the placenta undergoes dramatic transformations in form and function to act as the lungs, gastrointestinal system, kidneys, and liver of the fetus.[32] The villous, hemochorioallantoic placenta interfaces the pregnant woman and the fetus to mediate the exchange of oxygen and carbon dioxide and the secretion of hormones, growth factors, and cytokines; it provides nutritional supply and brings about the elimination of critical waste, which is important for fetal development.[33,34]

Many of the diverse activities that the placenta is responsible for are encapsulated in the villus.[3] The interaction with the maternal endometrium modulates maternal physiology and metabolism. Recent research has indicated that the placenta stimulates its own development by upregulating gland activity in response to endocrine signals.[35] It has been recognized that there is a more interactive dialogue between the placenta and the maternal tissues than previously considered. The definitions of the placenta are changing, and this unique organ is being reconsidered on a physiological rather than a structural basis.[34]

The placenta is also an immunologically active organ that carries the fetal genome and can therefore act as an allograft.[25-27,30] The immunologic paradigm of pregnancy was first described by transplant immunologist Sir Peter Medawar,[36] who observed the antigenic mixture of the fetus containing paternal antigens that are not rejected by the maternal immune system. T-cell recognition of paternal alloantigens creates a condition for alloimmunization, which is best demonstrated by the Rhesus D

incompatibility.[37-39] Accordingly, ingestion of the placenta could trigger alloimmunization, which may cause harm in future pregnancies.[30,40,41]

Modes of ingestion for placentophagy

The placenta can be eaten raw, cooked, roasted, dehydrated, or encapsulated or can be consumed through smoothies and tinctures.[4,5] The most frequently used preparation appears to be encapsulation after steaming and dehydration (Figure 2); placenta capsules can also be created through processing of the raw organ.[5] Numerous companies offer to prepare the placenta for consumption, although there are no uniform standards for the encapsulation process.[42]

For the process, the frozen placenta is rinsed in water, stripped of membranes, cleaned, sliced, steamed, and dehydrated at 115−160°F (46−71°C) and then ground and placed into 115−200 gelatin capsules that are stored at room temperature.[43-45] The heating process is of particular importance since it is well known that heating at 130°F (54°C) for 121 minutes is required to reduce *Salmonella* bacterial counts by 7 $\log_{10}$ in food.[46]

Proponents of the encapsulation method argue that this technique offers preservation of all benefits that the placenta has to offer. However, there are data showing that some nutrients (eg, iron) are likely to be lost during processing and encapsulation, so that the ingested amount is unlikely to have relevant biological activity or any clinical benefit.[47]

Some women eat slices of the placenta raw directly after birth, while others deep-freeze them for later consumption. Placental material might also be mixed with fruits or juices to create smoothies that mask the unpleasant taste or might be used as a meat substitute for recipes such as lasagna or pasta.[44,48]

A variety of providers offer placenta encapsulation and certification. Placenta Benefits (PBi) Ltd offers a network of almost 100 collaborators for placenta encapsulation in the United States and more in Canada, Australia, New Zealand, the United Kingdom, Malaysia, the United Arab Emirates, and Spain.[45] The owner of PBi published the often-cited survey on women's self-reported motivations and experiences with placenta encapsulation.[4] The cost of placenta encapsulation ranges between $200 and $400.[45,49]

Most encapsulation providers also offer so-called certification programs for individuals who seek to become providers of placenta encapsulation. These courses are mostly organized in modules of 12−16 weeks, for 6−9 months in total, including the supervised encapsulation of 3 placentas with patient feedback. The costs of such a certification program vary from $320 to $530 per person to become certified.[45]

No proven benefits of placentophagy

Despite the apparent interest in the United States, there are no known scientifically proven benefits of human placentophagy. In contrast, proponents of placentophagy claim several supposedly positive effects, such as prevention of postpartum depression, generally improved mood and energy, improved milk supply, availability of important micronutrients, and reduction of postpartum bleeding.[4,42]

In animals, some of these benefits might be derived from the high estrogen and lactogen content of the placenta.[8] Others, especially immunological benefits, might be induced by factors that prevent antibody response to fetal antigens.[8] Estrogen has good bioavailability, but whether the oral intake of human placental lactogen induces hormonal effects remains unknown.[50]

One study that explored human placental lactogen plasma levels in a sample of 8 lactating women showed that they were related to a change in breast size and the cross-sectional area of the areola but not to lactation.[51] Estrogen and progesterone, which can be found in abundance in the placental tissue, suppress the immunological processes involved in tissue rejection.[23,52] The ingestion of placental tissue may theoretically immunize the mother against placental cells remaining in utero after delivery, which could eventually pose a threat to the mother and lead to choriocarcinoma.[34,53]

FIGURE 2
Placenta capsules

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In addition, the alleged immunological benefits of placentophagy might be induced by factors that prevent antibody response to fetal antigens.[8] However, these are just theories, and there is currently no scientific evidence to support them.

Kristal and colleagues[8,54] demonstrated that ingested placenta enhanced opioid-mediated neurochemical pain thresholds in rats. Similar enhancement was demonstrated with ingested amniotic fluid.[55] The ingestion of amniotic fluid at delivery is at least as widely represented in mammals as placentophagy, owing to self-licking of the urogenital area, as well as licking and grooming of the neonate by the dam.[17]

Researchers started using the term placental opioid-enhancing factor (POEF) to refer to the placental component that induces this enhancement.[56] The idea that the POEF effect reduces pain sensitivity explains why most mammals engage in placentophagy. The molecular structure of POEF has not yet been identified; however, it is suggested that it is a relatively small peptide of 6000−8000 Daltons that can easily be inactivated at temperatures above 104°F (40°C).[17,56]

The only available randomized, double-blinded, placebo-controlled trial in women who ate their placenta compared the effect of placenta pills on maternal postpartum iron status.[57] Hemoglobin, transferrin, and ferritin were measured at 36 gestational weeks, within

TABLE 1
Alleged benefits of placentophagy in humans

Benefit	Study	Year	Design	Patients, n	Major finding	LOE	GR
Stabilization of mood	Selander et al[4]	2013	Self-reported survey	189	40% of responding patients reported stabilization of mood	IV	C
	Young et al[23]	2016	Descriptive laboratory study	28[a]	57% of analyzed placentas with detectable concentrations of steroid hormones	IV	C
Increase of lactation	Selander et al[4]	2013	Self-reported survey	189	15% of responding patients reported increase of lactation	IV	C
	Sykova-Pachnerova et al[100]	1954	Randomized controlled trial (major limitations)	210	86% of patients reported good or very good increase in milk production	IIb	B
Increase of energy	Selander et al[4]	2013	Self-reported survey	189	26% of responding patients reported increase of energy	IV	C
Increase of micronutrients	Gryder et al[57]	2017	Randomized controlled trial	23	No significant improvement of maternal iron status through intake of placenta pills	Ib	A
	Young et al[69]	2016	Descriptive laboratory study	28[a]	Daily intake provides 24% RDA for iron, 7% Se, 1.5% Zn; toxicity below threshold	IV	C

No human study was available for reduction of pain,[b] reduction of bleeding,[b] shrinking of uterus,[b] boosting of immune system, enhancement of bonding, treatment of insomnia, avoidance of scars, reduction of inflammation, regulation of hormones, or delay of aging.

GR, grade of recommendation; *LOE*, Oxford level of evidence; *RDA*, recommended dietary allowance; *Se*, selenium; *Zn*, zinc.

[a] Placenta samples; [b] Animal studies are available.

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96 hours postpartum, between days 5 and 7 postpartum and during week 3 postpartum in 10 women who received placenta pills and 13 women who received placebo. The authors found that the average iron concentrations were considerably higher in pills that contained placenta than in the placebo. Interestingly, there was no statistically significant difference in maternal iron status between the placenta supplement group and the placebo group.[57] The daily intake of placenta pills provided only 24% of the recommended daily iron intake for lactating women.[57] Results of a larger umbrella study are allegedly awaited.

Overall, the evidence for positive effects of placentophagy in humans is either anecdotal or limited to self-reported surveys. As shown in Table 1, very few studies have been conducted, and those available are often of poor quality. Controlled clinical trials of placentophagy confront a number of design-related challenges.

Ingestion of human material hinders the ability to standardize the preparation and amount of placenta that is ingested. A more important challenge would be bias: women who want to engage in placentophagy would belong to a self-selected group of subjects who have expectations of benefit and, therefore, an a priori positive attitude toward ingesting the placenta. Further bias may occur to avoid emotions that can result from regretting a decision; when expected outcomes do not occur or adverse outcomes occur, women might become less likely to report negative or no effects. The placebo effect is likely to be observed in such situations. Responsibly managing these challenges to study design may be impossible.

Harmful effects of placentophagy

Recently the Centers for Disease Control and Prevention (CDC) published a case from the Oregon Health Authority regarding a term infant who was readmitted because of late-onset group B *Streptococcus agalactiae* (GBS) sepsis 5 days after completion of the treatment for early-onset GBS sepsis.[58] The mother had been consuming placenta capsules 3 times daily. Her breast milk did not yield GBS, but the dried placenta inside the capsules was tested positive for GBS. Whole genome sequencing revealed that the GBS isolates from the first and second sepsis were identical to those from the placenta capsules. Although the infection could have come from another family member, this report is the first solid evidence that contaminated

placenta capsules can be a source of infection.[58]

The CDC hypothesized that heating for a sufficient time at a temperature adequate to decrease GBS bacterial counts might not have been carried out in this case.[58] Their idea is supported by studies that report the presence of a unique low-abundance microbiome in the healthy human placenta.[59,60]

On the one hand, it seems likely that placenta consumption could spread infections in women with acute chorioamnionitis and that this may be harmful to the mother and the newborn infant. On the other hand, a recently published study challenged the concept of the placental microbiota, reporting no difference between bacterial DNA in placental samples and in the contamination introduced during DNA purification.[61]

Inadequate heating and preparation of the placenta may also be insufficient to eradicate viruses such as HIV, hepatitis virus, or Zika virus.[60,62-64] It has been studied that the most common viruses in food products can only be eliminated by thermal processing methods.[65] Inactivation of hepatitis A virus required temperatures of 158°F (70°C) for 4 minutes; inactivation of norovirus and rotavirus requires even longer exposure to heat (30 minutes).[65-67] Research that evaluated the inactivation of HIV by pasteurization of breast milk showed that HIV is heat sensitive at temperatures between 133°F and 144°F (56−62°C).[68] It is unclear whether most encapsulation providers follow these preparation standards, which are obligatory to prevent viral persistence after steaming and dehydration.

Another concern about the harmful effects of human placentophagy involves the toxic substances that could accumulate in the placenta. A recently published study found cadmium, a heavy metal, in a low but detectable amount within processed placenta pills.[69] Women who ingest multiple pills may risk cumulative dosing. Accordingly, toxic components of tobacco, alcohol, or controlled substances could accumulate and harm the mother and the newborn infant through placenta consumption.[69-71] The frequently reported headaches by women who consume placenta could be associated with the accumulation of these toxic substances.[4]

Young et al[23] reported that bioactive hormones such as estradiol, progesterone, and allopregnanolone can survive the encapsulation process and might reach effect thresholds after placenta consumption. Although the majority of the 17 hormones analyzed were found to be below the estimated intake from the maximum recommended dose of placenta capsules, the mean concentrations of 3300 mg of placenta capsules could have a physiological effect.[23] There is no evidence to suggest that these hormones can actually be absorbed; however, this study lends support to the idea that hormones may persist and potentially reach physiological effect thresholds. Whether hormonal effects could contribute to the reduction of postpartum depression or to the risk of thromboembolic events has not been evaluated.

With regard to all these potential harmful effects, it should clearly be stated that the currently available self-reported surveys may be underestimating the harmful effects of placentophagy because women who have eaten their placenta may not report all instances of adverse outcomes. So far, reports remain anecdotal, and no well-designed study has evaluated the potential harm that might be induced by this practice.

Pathological examination of the placenta

A necessary condition for placentophagy is placental release from the hospital. However, it should be considered that once the placenta is released, it is no longer available for histopathological examination. Submissions of specimens to pathology are regulated on the federal and local level. In addition, the Joint Commission (www.jointcommission.org) states that all tissue removed from the body must be submitted to the Department of Pathology, with any exceptions being clearly stated as policy by the Medical Board or other governing body of the hospital.[72]

The placenta is the only major organ that is not routinely submitted for pathological examination, but most hospitals have in-house guidelines for submission of the placenta to the Department of Pathology in case of certain abnormalities.[72,73] The Joint Commission does not define normal; however, there are nationally accepted guidelines that specify which placentas should be submitted to Pathology.[72,74] These indications are listed in Table 2.

For pathological examination, the placenta is usually fixed in formalin or a similar fixative. Owing to the potential toxic effects of formaldehyde, the nonsterile transportation, delay of examination, and liabilities that require specimen retention, the placenta cannot be released from the hospital after submission to Pathology.[73,74] Women who want to engage in placentophagy should be aware of the consequence that pathological examination prevents placental release, preparation, and consumption.

Most placentas are normal and do not require pathological examination.[74] However, in a number of conditions, such as intrauterine growth restriction, preterm birth, and stillbirth, placental examination may reveal the underlying etiology and pathological processes that could have contributed to or caused adverse outcomes.[75-77] Acute and chronic inflammation conditions in the placenta that are associated with fetal morbidity and mortality can be identified through examination.[78-80] Moreover, abnormalities associated with placental implantation are of interest.[81,82]

Histopathological examination of the placenta can determine the cause of possible adverse outcomes. Women should therefore be thoroughly counseled about the importance and implications of the pathological examination of their placenta and that understanding of adverse outcomes, as well as future care, may be impaired by the inability of placental examination.

This is of interest because this examination could identify underlying and previously unknown medical conditions of the mother or child, including those

TABLE 2
Indications for histopathological examination of the placenta[75,85,87,101]

Maternal	Fetal/neonatal	Placental
Pregnancy-induced hypertension, preeclampsia, chronic hypertension with IUGR, HELLP syndrome	Small-for-gestational-age neonate or neonate with IUGR	Abruption of the placenta, placenta accreta/increta/percreta
Intrapartum fever or sepsis	Iatrogenic or spontaneous prematurity birth <37+0 gestational weeks	Abnormal macroscopic appearance (eg, infarct, mass, thrombosis, hemorrhage, malodorous, scar, retroplacental hematoma, abnormal color, placental lesions)
Maternal infection (eg, HIV, syphilis, CMV, primary HSV, toxoplasma, rubella)	Neonatal disease with possible intrauterine origin (eg, infection, sepsis, seizures, neurologic signs)	Inadequate small or large placental size or weight for gestational age
Maternal disease (eg, uncontrolled preexisting or gestational diabetes, anemia, seizures, malignancy, metastatic disease, collagen and autoimmune disease)	Monochorionic twins, twins with undetermined chorionicity, discordant twin growth,[a] twin-to-twin transfusion syndrome, high-order multiples[b]	Abnormal umbilical cord (eg, thrombosis, torsion, knot, SUA, absent Wharton's jelly, abnormally coiled cord, inadequate short or long length of the cord)
Prolonged rupture of membranes (>24 h) or premature rupture of membranes (>36 h)	Fetal hydrops, stillbirth, neonatal death	Suspected or obvious vasa previa or velamentous cord insertion
Drug, alcohol, or medication intake during pregnancy	Distress requiring NICU admission (eg, Apgar ≤6 at 5 minutes, arterial cord pH ≤7.0, ventilation, anemia)	Invasive procedures with suspected placental injury
Pregnancy duration <37+0 gestational weeks or ≥42+0 gestational weeks	Large-for-gestational-age fetus with birthweight >95th percentile	Suspected or obvious chorioamnionitis
Unexplained pregnancy complications (eg, preterm birth, fetal demise, stillbirth, spontaneous abortion)	Major congenital anomalies, dysmorphic phenotype, abnormal karyotype	Suspected incompleteness of the placenta or membranes
Unexplained ante-/intrapartum hemorrhage or increased bleeding (>500 mL)	Neonatal anemia or hemorrhage	Medical request
Severe maternal trauma	Thick or viscid meconium	
Previous maternal isoimmunization (eg, rhesus)	Oligo- (AFI <5 cm) or polyhydramnion (AFI >25 cm)	

AFI, amniotic fluid index; *CMV*, cytomegalovirus; *HELLP*, hemolysis, elevated liver enzymes, and low platelet count; *HIV*, human immunodeficiency virus; *HSV*, herpes simplex virus; *IUGR*, intrauterine growth restriction; *NICU*, neonatal intensive care unit; *SUA*, single umbilical artery.

[a] >20% variation in fetal growth between both twins; [b] Triplets, quadruplets, quintuplets, etc.

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that might recur and therefore might be helpful in future pregnancies. Such diagnostic findings enable recommendations to be made that could be important for the initiation and clinical management of subsequent pregnancies.[83-85]

Both staff and patients should be aware that dividing the placenta (and even cutting off a small piece for ingestion) eliminates the analysis of placental completeness.[86] Most importantly, individuals untrained in placental pathology will likely not recognize lesions or abnormalities that could be of marked clinical significance. Inadvertent removal of such lesions may never result in their diagnoses. In addition, bacterial and viral cultures require fresh placental tissue.[87] The indications for the examination of the placenta should individually be discussed with the mother, and health care organizations should develop clear clinical guidelines to address patient requests to take the placenta home (Table 2).

Legislation and regulation on placental release

Most states in the United States lack clear regulations and safety guidelines that address placentophagy. As a result, current health policy at the state level appears to allow placental release and consumption, under the general rule that what is not explicitly prohibited is permitted. However, the US federal law, the Medical Waste Tracking Act (MWTA) of 1988,[88] defines all tissues, organs, and body parts that are removed during surgery or autopsy, but not examined as specimens, as medical waste. Regulations have been passed by states, counties, and cities regarding the proper handling and disposal of medical waste. Violation of the MWTA carries penalties.

Hospitals have made their own policies regarding the release of the placenta that vary widely among various hospitals. Some adhere to the MWTA and strictly refuse releasing the

placenta from the hospital, considering it as a potential biohazard. Others allow placental release if the placenta does not need to be pathologically examined. In 2013, a survey among perinatal pathologists in the United States and Canada identified that 61% of pathologists allow placental release from the hospital, with burial being the most frequent patient request.[73]

The states of Hawaii, Oregon, and Texas explicitly allow mothers to take their placentas home from the hospital.[89-91] Mississippi has recently abandoned the definition of medical waste for the placenta, which also legalizes placental release upon request. This was achieved through the initiative of a 25 year old mother who wanted to engage in placentophagy and went to court to take her placenta home.[92]

In facilities in which placental release is allowed, women need to test negative for infectious diseases, and specimen release forms need to be signed by the patient and the physician. The waiver releases the hospital from liabilities that may occur if the placenta carries an infectious disease, which then induces cross-contamination, or if toxic substances cause illness to the recipient. Whether these waivers might survive scrutiny in future litigation is unknown. The placenta needs to be placed in special biohazard bags before it is given to the mother. The estimated number of cases in which women sneak their placenta out of the hospital without medical staff noticing is, of course, unknown.

Is the placenta food?

In 2007, the US Food and Drug Administration (FDA) issued a warning letter to a firm stating that its dietary supplement was adulterated because it contained human placenta, which was not considered to be a dietary ingredient.[93] Apart from this one warning letter, the FDA has not yet issued regulations for placental processing, arguing that food does not need to be approved before it is commercially sold in the interstate commerce (FDA email communication, May 2017).

The FDA also released a statement that placental tissue does not belong to any of the dietary ingredient categories defined in section 201 (ff) of the Federal Food, Drug and Cosmetic Act, which states that manufacturers of food are responsible for complying with the requirement of the Act that food must be "wholesome and safe for human consumption."[94,95] It appears that the FDA currently does not consider the placenta to be food, but it has not yet regulated the encapsulation process.

In Europe, the Food Standards Agency (FSA) that represents England, Wales, and Northern Ireland on food safety announced in June 2014 that they were going to consider the human placenta as "novel food" under the European Union Council Regulation 258/97.[96] Because this regulation could ban the sale of placenta capsules, it encountered heavy resistance among proponents and providers of placenta encapsulation.

The Independent Placenta Encapsulation Network (IPEN) started a petition against this regulation and submitted a dossier to the FSA. IPEN argued that the placenta is not commercially sold but is processed for personal use, which would stand in accordance with European Union regulations (eg, regulation number 178/2002). If the placenta is regarded as food, mothers and providers who are involved in encapsulation would be at risk for prosecution. At present, the human placenta does not appear on any official list as food, and the FSA has not yet reached a final decision.

Implications for professionally responsible patient counseling

Based on the preceding scientific and clinical review, 2 ethical considerations emerge, both based on a preventive ethics approach to decision making with patients.[97-99] The first is whether there is a professional responsibility to offer placentophagy, and the second is how to respond to expressions of interest in placentophagy or requests to obtain the placenta for this purpose.

Clinical management should be offered when there is a reasonable expectation of net clinical benefit in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment. Based on the previously cited scientific and clinical review, claims for clinical benefit to the mother from placentophagy lack a reliable evidence base. Therefore, there is no professional responsibility to offer access to the placenta for placentophagy.

Clinical management should be recommended when there is a reliable evidence base that such management is clinically superior. Based on the previously cited scientific and clinical review, there is no such evidence for placentophagy. Potential harmful effects of placentophagy have been reported and may be clinically significant.

The professional virtue of prudence cautions both the physician and patient not to take a risk of clinically significant harm in the absence of any clinical benefit. The physician should therefore engage in directive counseling by recommending against placentophagy and explain that this recommendation is based on lack of evidence and a prudence-based concern to prevent potentially significant clinical risk. This approach should be the same in legal jurisdictions that permit the woman to have access to her placenta for placentophagy.

Physicians have the professional responsibility to provide a preventive approach to the conditions for which placentophagy is believed to be useful and should inform women who experience adverse postpartum symptoms, especially signs of depression, that placentophagy has not been found to be helpful in treating postpartum depression and they should promptly contact their physician or midwife if postpartum depression occurs. The patient information sheet (Table A1) in the Appendix of this paper offers a document that can be distributed to patients indicating the risks and benefits of placenta consumption.

Conclusion

There is no scientific evidence of any clinical benefit of placentophagy, and there is evidence for an actual risk of harm. Based on this information, physicians and

other health care providers have no professional responsibility to offer placentophagy to their patients. There is a professional responsibility to respond to expressions of interest in placentophagy with directive counseling in the form of a recommendation against it. ■

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Appendix

TABLE A1
Patient information sheet on placenta consumption

Recommendation	
Given documented harms and unproven benefits placenta consumption is discouraged.	
Important information	
Benefits of placenta consumption have been reported in surveys, which are insufficient in making reliable recommendations. No controlled scientific studies have been performed on whether placenta consumption offers any benefits, but there are reports of possible harm.	
Pathological examination of the placenta can be important for the health of the mother and the baby and for future pregnancies. If the placenta needs to undergo pathological examination, mothers will not be able to take the placenta home for consumption. Also, if the placenta is taken home and consumed, the placenta becomes unavailable for any pathological examination in case of problems.	
Risks	**Benefits**
There is evidence that mothers who have eaten their placenta can spread serious bacterial infections to their baby and may develop infections themselves.	There are anecdotal reports that mothers who have eaten their placenta have improved mood and less baby blues after giving birth, but there are no studies confirming these observations.
Viral infections can also be spread to the baby if the mother is infected and if she then eats her placenta.	There are anecdotal reports that mothers who have eaten their placenta have better milk supply, but there are no studies confirming these observations.
There is evidence that the placenta contains toxic substances, which may be deleterious to the mother and can be passed to the baby during breast-feeding in mothers who eat their placenta.	There are anecdotal reports that mothers who have eaten their placenta have more energy and less fatigue than they expected after giving birth, but there are no studies confirming these observations.
There is evidence that the placenta contains bioactive hormones, which might be harmful to mothers who eat their placenta.	There are anecdotal reports that mothers who have eaten their placenta have less pain and decreased use of pain medication after giving birth, but there are no studies confirming these observations.
There is evidence that mothers who have eaten their placenta do not have a better iron status than those who have not eaten their placenta.	There are anecdotal reports that mothers who have eaten their placenta have alleviated postpartum bleeding and discharge after giving birth, but there are no studies confirming these observations.

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