

Managing Costs in High Risk Obstetrics: The Value of Technology that Improves Diagnostic Accuracy

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Introduction

In the USA, about 12.8% of babies (more than half a million a year) are born prematurely. The rate of premature birth has increased by 36% since the early 1980's, [1] and is now responsible for an estimated \$26 billion in costs to the American healthcare system annually [2]. Unfortunately, little progress has been made to decrease prevalence in so serious condition.

From a managed care perspective, a premature birth constitutes a potential high cost episode of care and high-risk pregnancies constitute a major category of high-cost for payers. In Medicaid, 27% of all inpatient charges and 60% of all hospital procedures covered by Medicaid [3] are related to pregnancy and although only 10% of pregnancies are considered high risk, they account for 57% of total newborn costs [4]. A recent analysis found that overall, 4% of the Medicaid population was responsible for 48% of program spending in 2001 [5]. These high-cost members translate into highly concentrated spending on only a small fraction of the entire population.

In this paper we will identify ways in which new technology can improve the diagnostic accuracy of pregnancy-related disorders and assist in managing the costs of high risk obstetrics.

High Risk Pregnancy and Preterm Birth

A pregnancy is considered high-risk for a variety of reasons, generally categorized into those of maternal or fetal origin. Prevalent maternal factors include age (younger than age 15, older than age 35); weight (pre-pregnancy weight under 100 lb or obesity), medical comorbidities and a history of complications during previous pregnancies, among others. Prevalent fetal factors include exposure to infection (herpes simplex, viral hepatitis, mumps, rubella, etc.), exposure to addictive substances (cigarette smoking, alcohol intake, and illicit or abused drugs), and exposure to a variety of medications.

Preterm birth is defined as delivery before 37 weeks of gestation. It is the leading cause of neonatal death and infant mortality, often as a result of respiratory distress syndrome due to immature lung development [6]. Babies who survive are also at high risk of neurological disability [7] and can experience further breathing, feeding, digestive, visual, and hearing problems. Observational studies have found that a prior history of preterm birth significantly increases the risk of another in a subsequent pregnancy [8].

Identifying Areas for Improved Management of Preterm Birth

Births that follow spontaneous preterm labor (PTL) and preterm premature rupture of membranes (pPROM) are together designated as spontaneous preterm births. Spontaneous preterm births account for ~70% of all premature deliveries, where the remaining 30% are indicated as a result of maternal or fetal infection [9]. Of those births classified as spontaneous preterm births, 64% are the result of preterm labor (PTL) and 36% are the result of preterm premature rupture of membranes (pPROM).

PTL is defined as the onset of active contractions at a preterm

(<37 weeks) gestation. Common symptoms suggestive of PTL include: uterine activity, abdominal discomfort, change in vaginal discharge, bleeding and/or cramping. Traditional evaluation includes uterine activity monitoring and evaluation of the cervix [10]. The exact mechanism(s) of preterm labor is largely unknown, but is believed to include: decidual hemorrhage, (e.g. abruption, mechanical factors such as uterine over-distension from multiple gestation or polyhydramnios), cervical incompetence (e.g. trauma, cone biopsy), uterine distortion, cervical inflammation, drug abuse, smoking, alcohol consumption, among others [11].

PPROM is defined as spontaneous rupture of the membranes at less than 37 weeks of gestation at least one hour before the onset of contractions. Common symptoms include complaints of leakage in the absence of active labor. Traditional diagnostics methods include nitrazine/pH, ferning, and ultrasound. Indigo carmine intra-amniotic injection may be indicated if status remains questionable after all other methods are performed [12].

The exact mechanism(s) of PPRM is largely unknown, but is believed to include: bacterial production of proteases and phospholipases, host response to blood or bacteria resulting in leukocyte activation and cytokine release, weakness from over distention, strain from preterm uterine activity, direct membrane trauma (cerclage or amniocentesis), or a developmental weak spot [13].

Preterm Labor (PTL) Diagnostic Methods: Improvements and The Associated Cost Impacts

Improved diagnostic methods leading to improved management can directly impact the 70% of spontaneous preterm births caused by both PTL and PPRM. The past decade has seen major developments in the diagnosis of both conditions, the latter of which is now increasingly considered by managed care.

The ability for a clinician to diagnose true PTL has taken significant strides in the past two decades with the advent of the fetal fibronectin (fFN) biomarker test. The presence of fFN in the vagina after the twentieth week is abnormal and may indicate disruption of the attachment of the fetal membranes between the uterine wall and the deciduas [14]. Prior to the availability of this assay, discerning true preterm labor from false preterm labor depended on multiple methods that were neither sensitive nor specific enough to accurately predict a time to delivery for the patient presenting with complaints of early

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Received November 08, 2012; Accepted December 17, 2012; Published December 27, 2012

Citation: Lopes M (2013) Managing Costs in High Risk Obstetrics: The Value of Technology that Improves Diagnostic Accuracy. J Women's Health Care 2: 120. doi:10.4172/2167-0420.1000120

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contractions. These methods consisted of home uterine monitoring and cervical length measurements. While they had good predictive values for obvious cases (i.e., uterine contractions or cervical changes), they did not serve a useful function in predicting time to delivery in the absence of pronounced symptoms.

With the FDA approval of the fFN test (Adeza Biomedical, Sunnyvale, CA) in 1997 [15], this situation changed due to the high negative predictive value (99.5%) of the test for delivery within 14 days [16]. Historically, the suspected PTL patient typically translated into unnecessary home uterine activity monitoring, potential admissions and hospitalization. With the use of the fFN test, however, evaluation of the patient was changed to a screening process that resulted in the clinician's ability to reduce uncertainty and confidently rule out PTL with a negative result.

Cost-saving implications of this test on the diagnosis of preterm labor can be seen in both the avoidance of unnecessary hospital admissions, as well as unnecessary patient transfers from a medical center of lower trauma level classification to one with a higher trauma level. Joffe et al. [17] reported a savings in hospital admissions costs of \$486,000 annually as a result of the fFN test [17] and Giles et al. [18] reported a 90% reduction of transfer costs with the use of the fFN test [18].

Preterm PROM (PPROM) Diagnostic Methods: Improvements and The Associated Cost Impacts

Over the past century, countless approaches have been proposed for the diagnosis of premature or pre-labor rupture of the fetal membranes (PROM) [19,20]. As was the case for PTL, the diagnosis of PROM when symptoms are pronounced (i.e., gross rupture of membranes with obvious fluid leakage) is easy to make. However, in 40-47% of patients presenting with suspicion of ROM, obvious leakage from the cervix cannot be visualized and the diagnosis becomes difficult to confirm or rule out [21,22].

As demonstrated in table 1, standard diagnostic methods, including nitrazine, ferning pooling and ultrasound, alone or in combination with one another, have proven inaccurate in such cases. In the absence of an accurate test to diagnose or rule out ROM, the patient is at a greater risk for not receiving the necessary interventions, including appropriate use of steroids. Failure to implement salutary measures can have both significant medical and financial implications for the payer, the mother and baby, as well as for the hospital and the obstetrician. Conversely, a false positive diagnosis can lead to unnecessary hospitalizations and induction of labor.

As table 1 shows, with the advent of the biomarker test based on the detection of placental alpha microglobulin-1 (PAMG-1) (marketed as the AmniSure® ROM Test, manufactured by AmniSure® International LLC, Boston, MA), the clinician now has the ability to diagnose ROM with a rapid, non-invasive, highly sensitive and specific test in the 40-47% of ROM cases that are not obvious. PAMG-1 is a decidual protein with very high concentrations in amniotic fluid with extremely low concentrations in background cervico-vaginal secretions.

Significant financial impact results from the use of the PAMG-1 test primarily due to: (i) reductions in costs associated with false diagnoses using traditional methods and (ii) reductions in current spending on ROM diagnosis in non-obvious cases using traditional methods.

Costs of Inaccurate Diagnoses

When used alone, or in combination, traditional methods

result in high costs due to their poor accuracy, especially when used on non-obvious cases (Table 2). This leads to important economic considerations surrounding the implications of false diagnoses including (i) costs associated with false negative diagnoses that result in the failure to treat in a timely manner and (ii) costs associated with false positive diagnoses that result in unnecessary admissions and unwarranted induction of labor.

Costs of False Negative Diagnoses

Currently, there are two main treatments used on patients with the diagnosis of PROM: prophylactic antibiotics, to fight infection and prolong latency, and corticosteroids, to help mature the fetal lungs in anticipation of a preterm birth. Table 3 summarizes multiple randomized-controlled trials that have demonstrated that antibiotics have a significant impact on the reduction of various conditions that may result as a consequence of PROM including maternal chorioamnionitis and neonatal infection [37]. Failure to administer antibiotics could result in increased risk of infection that could have otherwise been prevented or treated via the timely administration of antibiotics. By reducing the incidence of these conditions through the opportune administration of antibiotics, the costs associated with these conditions may be reduced.

As shown in table 3 and demonstrated in multiple randomized controlled trials, corticosteroids also have a significant impact on the reduction of the various conditions that may result as a consequence of PROM including: fetal and neonatal death, respiratory distress syndrome (RDS), intra-ventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), systematic infection within 48 hrs, and cerebral palsy (CP) [39]. The model depicted in table 3 illustrates real-life DRG payments for the various outcomes associated with PROM that corticosteroid administration can improve. As a more specific and detailed example related to table 3, the incidence of RDS in neonates

Biomarker Test	Sensitivity (%)	Specificity (%)
PAMG-1 Immunoassay [23,24]	94 -100	99 -100
Traditional Test	Sensitivity (%)	Specificity (%)
Ferning [25,26]	51 - 63	71 - 76
Nitrazine (pH) [27]	88	68
Pooling, AFI, Ferning [26]	85	79
Pooling, AFI, Nitrazine [24]	72	98
Traditional Test	NPV %	Reference
Pooling, Nitrazine, Ferning [28]	46.5	Delivery <48 hrs
Pooling, Nitrazine, Ferning [29]	54.5	ROM

Table 1: Accuracies of Various ROM Methods in Non-Obvious Cases.

Procedure	Percentage of Patients with Non- Obvious ROM Procedure is Used On	CPT®/HCPCS	2011 Medicare Payment (per patient)
Speculum exam for ROM suspicion	100% [12]	CPT® 99218 [30,31]	\$68.81
Ferning test	100% [12]	Q0114 [30,32]	\$10.06
Vaginal pH/nitrazine test	100% [12,24]	CPT® 83986QW [30,31]	\$5.04
Ultrasound	100% [12,24]	CPT® 76805 [33,34]	\$149.84
Indigo carmine amnioinfusion	4.30% [24,29]	CPT® 59070 [35,36]	\$13.72
Total cost per non-obvious ROM diagnosis			\$247.47

Table 2: Costs of Making the Diagnosis of PROM in Non-Obvious Cases

born to a mother with PROM who did not receive corticosteroids is 34% higher than the incidence of RDS in neonates born to a mother with PROM but who did receive a course of corticosteroids. Consequently, for all cases of PROM detected by the PAMG-1 test that would have been undetected by traditional methods (see sensitivities in table 1); a 34% reduction in the rate of RDS could be achieved.

By reducing the incidence of the various conditions associated with PROM through an accurate and timely diagnosis that allows for the appropriate intervention, the costs associated with these conditions should also be reduced.

Costs of False Positive Diagnoses

PROM occurs in 10% of all pregnancies with approximately 3% occurring during preterm gestations and the remaining 7% occurring at term. Therefore, close to 70% of patients diagnosed with PROM will have delivery induced and approximately 30% will be admitted into the hospital.

Aside from the administration of treatments previously described, two main pathways exist for managing patients diagnosed with PROM: (i) for patients at term or late pre-term (≥ 34 weeks of gestation), induction of labor is recommended and (ii) for patients at less than 34 weeks of gestation, hospitalization and observation is recommended to allow gestation to prolong [12]. Depending on the gestational age of a patient falsely diagnosed with PROM, one of these two pathways would be unnecessarily followed.

As figure 1 shows that, 2-22% of cases will be falsely diagnosed by using various combinations of traditional methodologies, 70% of these cases will be induced at a cost of \$1,237.00 per induction [40], 17% of which will go on to have a C-section costing \$11,092.00 [41]. The remaining 30% of falsely diagnosed patients with a gestational age less than or equal to 34 weeks, will almost certainly be

hospitalized at a rate of \$1,620.00/day [42]. As is often the case, these patients may spend multiple days in the hospital before a diagnosis is established and discharge can occur.

Costs of Making ROM Diagnosis

Table 2 outlines the costs associated with the various procedures available for diagnosing ROM. A review of the reimbursement amounts issued by the Centers for Medicare and Medicaid Services (CMS), even after adjusting for the incidence of some of the less prevalent methods (i.e., indigo carmine intra-amniotic injection), the costs of performing a diagnosis per patient via the typical combination of traditional methods remains greater than the costs of using the PAMG-1 test (\$247.47 vs. \$90.64). It should be noted that this model does not take into account the multiple iterations that each one of these methods may undergo during the full course of evaluation, which could significantly raise the cost of making the diagnosis by traditional methods.

Conclusions

In early 2011, the widespread use and clinical effectiveness of the fFN and PAMG-1 assays were formally recognized by the authors of the Guidelines for the Management of Spontaneous Preterm Labor in the Journal of Maternal-Fetal and Neonatal Medicine [43]. They stated that “The PAMG-1 immunoassay is the most useful tool in determining women at high risk for PROM” and that “Ultrasonography to determine cervical length, fFN testing, or a combination of both are the most useful tools in determining women at high risk for preterm labor”.

Respected American organizations like the American Academy of Family Physicians [44] and guidelines like UptoDate [45] also mention the utility of the PAMG-1 assay in detecting PROM. Aside from improving quality and promoting evidence-based practice, payers benefit from the fFN and PAMG-1 tests because they directly translate

False Negative Rate of ROM Diagnosis of Trad. Methods [24,26,28,29]	Treatment	Condition	Incidence without Treatment	Incidence with Treatment	Incidence Reduction of Condition with Treatment	DRG Cost of Condition [38]
11%-28%	Antibiotics [37]	Maternal chorioamnionitis	25%	16%	34%	\$5,892
		Neonatal Infection	17	10	38	\$6,466
	Corticosteroids [39]	Fetal and neonatal Death	19	14	23	\$1,793
		Respiratory Distress Syndrome (RDS)	26	17	34	\$6,198
		Intra-ventricular Hemorrhage (IVH)	11	6	44	\$3,479
		Necrotizing enterocolitis (NEC)	6	3	54	\$3,479
		Systematic Infection within 48 hrs	9	5	44	\$6,198
		Cerebral Palsy (CP)	7	4	40	\$3,479

Table 3: Corticosteroids also have a significant impact on the reduction of the various conditions that may result as a consequence of PROM.

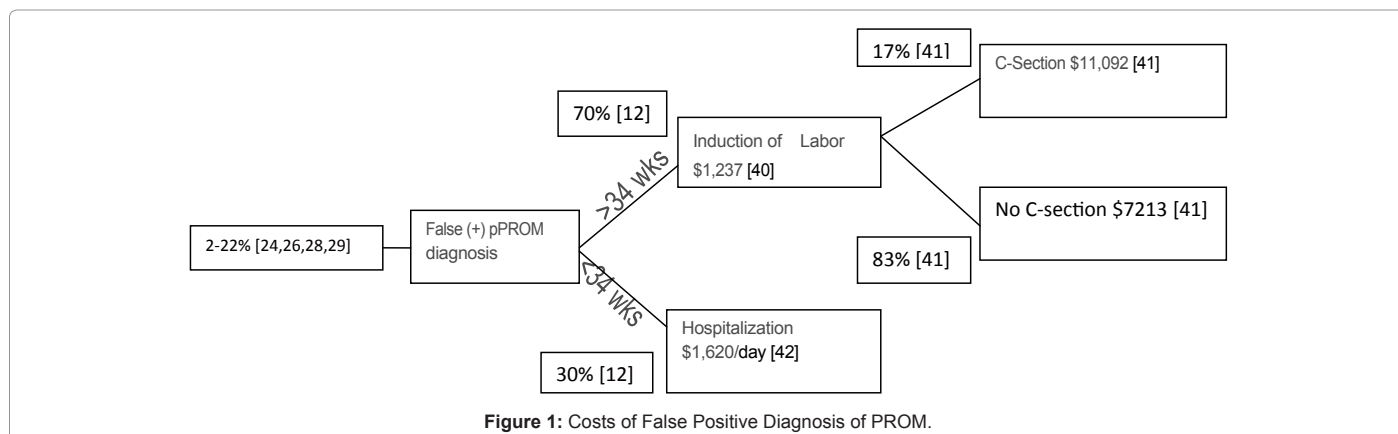


Figure 1: Costs of False Positive Diagnosis of PROM.

clinical advantages into potential cost reductions in the management of high risk patients.

The introduction of the fFN test into clinical practice preceded that of the PAMG-1 test by almost 10 years. Over this time, positive coverage determinations were issued by all major public and private payers on the use of the fFN test in the diagnosis of preterm labor (CPT® Code 82731; 1997) given its clinical utility and cost-effectiveness profile.

Similarly, PAMG-1, within the first few months of having been assigned a CPT® code (84112; 2011), has received positive coverage determinations by the majority of state Medicaid agencies and other private payers. Given the clinical and cost-effectiveness parallels that exist between the fFN test and the PAMG-1 test, it is expected that positive coverage for the PAMG-1 test will follow a similar path to that of the fFN test and evolve as the standard of care to improve diagnostic accuracy in ROM. In turn, this should reduce downstream costs through appropriate triage and management once an accurate diagnosis of PROM has been established.

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