

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 20, 2020

Progenity, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39334
(Commission
File Number)

27-3950390
(IRS Employer
Identification No.)

4330 La Jolla Village Drive, Suite 200,
San Diego, CA
(Address of Principal Executive Offices)

92122
(Zip Code)

Registrant's Telephone Number, Including Area Code: (855) 293-2639

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PROG	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On November 20, 2020, Progenity, Inc. (the "Company") made available a Preeclampsia R&D Day corporate presentation on the Company's website, which provides an overview of preeclampsia, its cost to the healthcare system, and the Preecludia™ preeclampsia rule-out laboratory-developed test, and issued a related press release announcing the clinical verification data for the Preecludia test currently in development. Copies of the corporate presentation and the press release are furnished herewith as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 8.01 and Exhibits 99.1 and 99.2 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibits 99.1 and 99.2 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Preeclampsia R&D Day Corporate Presentation, dated November 20, 2020](#)

99.2 [Press Release, dated November 20, 2020](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 20, 2020

Progenity, Inc.

By: /s/ Harry Stylli, Ph.D.

Harry Stylli, Ph.D.
President and Chief Executive Officer

Preeclampsia R&D Day

Mathew Cooper, PhD, MBA
Chief Scientific Officer

November 20, 2020

Forward Looking Statements

This presentation contains “forward-looking statements” within the meaning of the federal securities laws, which statements are subject to substantial risks and based on estimates and assumptions. All statements, other than statements of historical facts included in this presentation, including statements concerning our strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, estimates business trends, expected testing supply and demand, the anticipated timing, design and conduct of our planned clinical trials, the development of our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the pricing of our product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements implied in this presentation, including those described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Report on Form 10-Q for the quarter ended September 30, 2020, and elsewhere in such filings and in other subsequent disclosure documents filed with the U.S. Securities and Exchange Commission (SEC).

We cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the way expected. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the uncertainties, you should evaluate all forward-looking statements made in this presentation in the context of these risks and uncertainties and not place undue reliance on forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified by cautionary statements included in this presentation. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events, except as required by law.

Industry and Market Data: We obtained the industry, market, and competitive position data used throughout this Presentation from our own internal estimates and data, from industry and general publications, and research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information, industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our understanding of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and competitive position data included in this prospectus are based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to various factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Preecludia™ - A high Potential Rule Out Test for Preecl

- Established a fundamental understanding of preeclampsia and the great **clinic need** that exists today in assessing patient risk in our channel: Ob/Gyn and MI
- Showed the **incremental healthcare cost burden of \$9B+** associated with managing preeclamptic pregnancy and its support for premium reimbursement
- Shared our compelling prospective, blinded clinical verification data from 400 subjects for our Preecludia™ LDT rule-out test achieving **high sensitivity of 88%**, **98.2% NPV*** with a rule out window of up to 14 days
- Provided support for the **clinical utility** of a rule-out test and its place in the clinical management care path to help improve standard of care
- Demonstrated our ability to advance our program and our efforts to generate **adoption rates** within our women's health channel towards a \$3B US market

* NPV calculated using a 10% prevalence rate

Agenda

Opening remarks and Introductions



The Patient Burden, Eleni Tsigas, CEO of Preeclampsia Foundation



Introduction to Preeclampsia, Dr. Douglas Woelkers, MD



Preeclampsia Cost of Illness, Dr. Mathew Cooper, PhD, MBA



Preecludia™: The Development Journey from Bench to Bedside, Dr. Pankaj Oberoi, Ph.D



Preeclampsia: The Gravity of the Condition and the Unmet Need, Dr. Christopher Robinson, MD, M



Preecludia™: Clinical Evidence Development Program, Christina Settler, MS, CGC

Closing Remarks

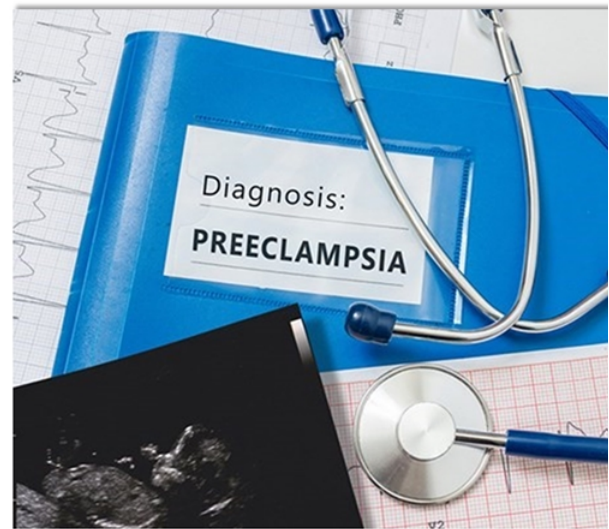
Introduction to preeclampsia

Douglas Woelkers, MD

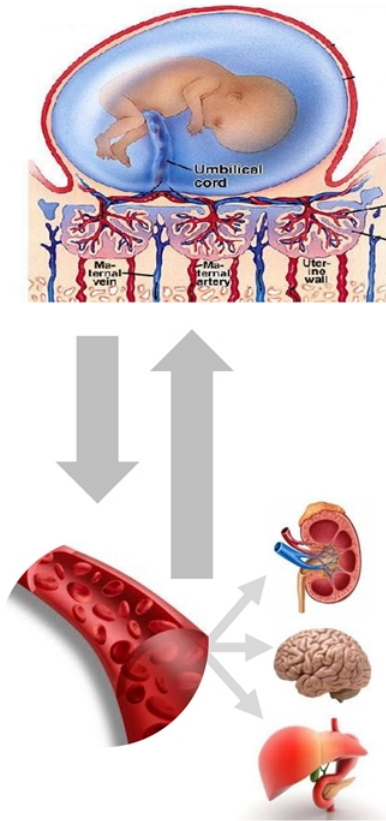
Professor Obstetrics, Gynecology, and Reproductive Science
University of California, San Diego

What is preeclampsia?

- A disease of pregnancy
- Characterized by
 - High blood pressure
 - Multi-organ injury
 - Fetal compromise
- Named for the syndrome that precedes *eclampsia* (seizures)
- Unique to humans
- Related to presence of placenta
- Resolves spontaneously after pregnancy



The pathophysiology of preeclampsia is complex



STAGE I – PLACENTAL

- Poor implantation
- Defective remodeling
- Perfusion mismatch
- Hypoxia, inflammation

“Toxins”

STAGE II – MATERNAL

- Endothelial dysfunction
- Vasospasm
 - Hypertension
- Capillary leak
 - Edema
 - Proteinuria

- Oxidative stress
 - Free radicals, lipid
- Prostaglandins
 - Thromboxane
- Cytokines
 - Tumor necrosis fa
- Activated neutrophil
- Placental debris
 - Trophoblast fragm
- Placental growth f
 - Angiogenic and ar
 - peptides

There are severe maternal and fetal consequences of pre

Maternal Impact

- ✓ Eclamptic Seizures
- ✓ Intracranial hemorrhage
- ✓ Posterior reversible encephalopathy
- ✓ Heart failure
- ✓ Pulmonary edema
- ✓ Acute renal failure
- ✓ Subcapsular hepatic hematoma
- ✓ DIC, hemorrhage
- ✓ Death



Fetal Impact

- ✓ Growth restriction
- ✓ Preterm birth
- ✓ Placental abruption
- ✓ Intrauterine hypoxia
- ✓ Fetal death



Preeclampsia can affect any pregnancy

- 3.75 million total births US, 2019
 - 3 to 8% of all births complicated by preeclampsia
 - 112,500 to ~300,000 cases per year
- Occurs in 2nd half of pregnancy
 - After 20 weeks
- Mostly diagnosed near term (37 to 42 weeks)
 - But disproportionate effect on preterm births

“ it is important to recognize that cases of preeclampsia in nulliparous women are often associated with other risk factors.”

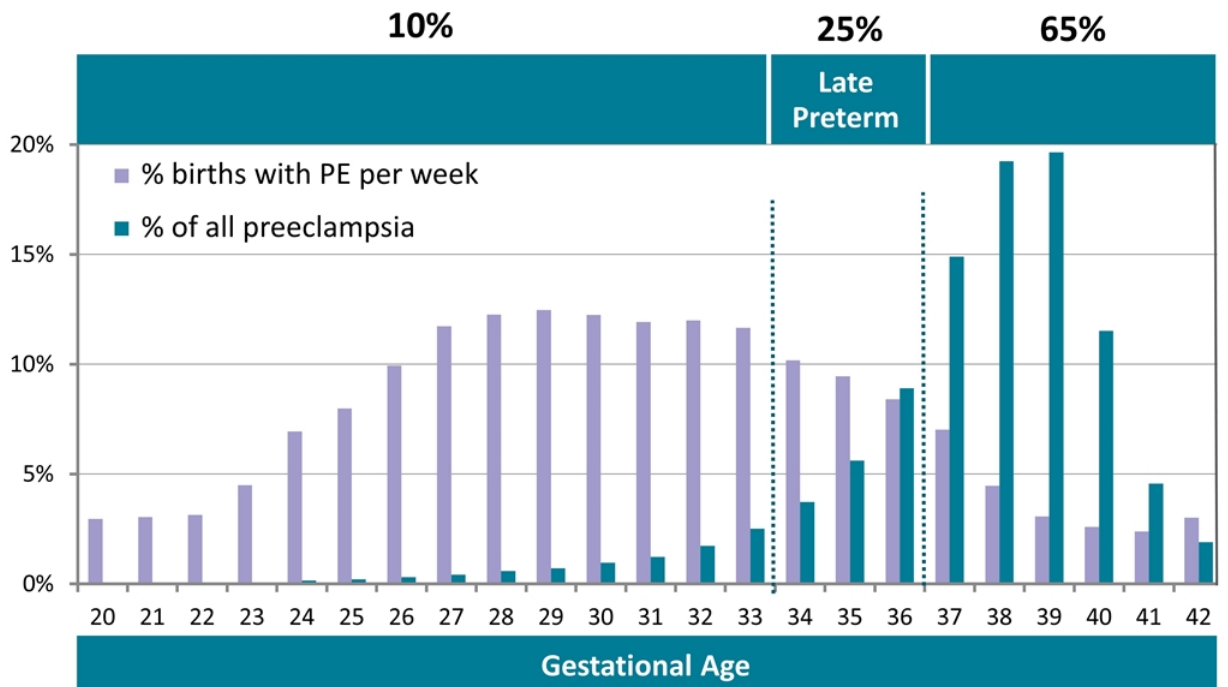
- ACOG Practice Bulletin

Reliance on maternal history and physical exam occasionally be problematic in practice.

Thus, an astute and thorough diagnostic approach and other corroborating findings when symptoms are mis-

Rates and incidence of preeclampsia by gestational week

Most preterm deliveries due to PE occur between GA 28-37 weeks



2009 Natality Statistics, CDC
 *Lain, et al. JAMA 2002

There are Many Risk Factors for Preeclampsia

Risk Factors for Preeclampsia	
First pregnancy	More than 5 pregnancies
Twins	Triplets
Older maternal age	Younger maternal age
Obesity	Low body mass index
Short inter-pregnancy interval	Long inter-pregnancy interval
New partner	Old partner
History of subfertility	IVF and surrogate pregnancy
Preexisting hypertension	History of preeclampsia
Family history of preeclampsia	Partner history of preeclampsia
Diabetes	Renal disease
Hyperlipidemia	Most concurrent medical diseases
Poverty	Race (African American)
Smoking	Cohabitation

- Between 8 - 20% of women have at least one risk factor³
- The risk of preeclampsia for women with one risk factor increases from 12% to 26%²
- The prediction of preeclampsia using risk factor models is Sensitivity 61% Specificity 75%

¹ North RA, et al. BMJ. 2010 Apr 7;342:1875.

² O'Gorman N, et al. Ultrasound Obstet Gynecol 2017.

³ Werner E, et al. Obstet Gynecol 2015.

The clinical and economic burden of preeclampsia is substantial and potentially underestimated

1 cause iatrogenic preterm delivery

- 42% of indicated preterm deliveries

1 indication for labor induction

- 25% of induced labors

2 cause of maternal mortality

- > 15% of direct maternal deaths
- 50-60 deaths/yr.

3 indication for antepartum admission

- 8.1% of admissions
- 1.1% of all pregnancies
- 20% of NICU admissions

Short Term Costs of Preeclampsia

Source Cost	Cost
Maternal per birth	\$19,075
Infant per birth	\$21,847
Combined per birth	\$40,922
Total cost	\$6.4 billion

¹ CDC Vital Statistics, 9/08.

² Hauth JC, et al. Obstet Gynecol 2000 Jan;95(1):24-8

³ Lydon-Rochelle, et al. Med Care 2007 Jun;45(6):505-512

⁴ Mackay AP, et al. Obstet Gynecol 2001 Apr;97(4):533-8

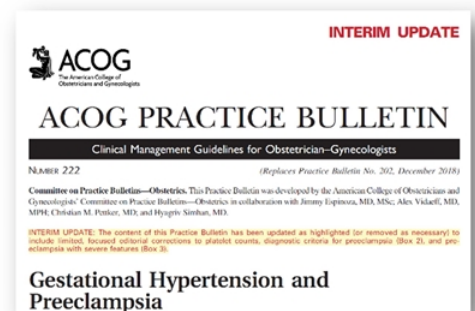
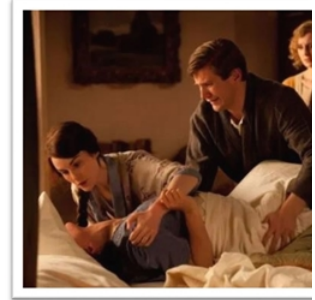
⁵ Sibai BM. Am J Obstet Gynecol 2004 Jun;190(6):1520-6

⁶ Stevens W, et al. Am J Obstet Gynecol 2017 Sep;217(3):237-48.

The diagnosis of preeclampsia is based on historical con

New hypertension with proteinuria or severe features

- **Hypertension**
 - Onset *usually* after 20 weeks
 - Systolic BP ≥ 140 , *and/or* diastolic BP ≥ 90
 - Sustained two resting measurements >4 hrs apart
- **Proteinuria**
 - 24-hour protein ≥ 300 mg
 - Protein: creatinine ratio ≥ 0.30
 - Spot sample ≥ 30 mg/dl
 - Dipstick $\geq 2+$
 - Discouraged for diagnosis, but acceptable for screening or if no other test
- **Severe features**
 - Markers of end-organ injury



The diagnostic features of preeclampsia poorly predict adverse outcomes

Feature	Adverse Outcome	+ LR	- LR
Headache	Composite	0.6 (0.3-1.1)	1.5 (1.0-2.3)
Visual disturbances	Eclampsia	2.5 (1.8-3.5)	0.2 (0.1-0.5)
Epigastric pain	Composite	0.3 (0.1-1.3)	1.3 (1.0-1.6)
Severe hypertension	Eclampsia	1.2 (1.0-1.4)	0.3 (0.1-1.0)
24-hour protein > 3 gm	Eclampsia	4.1 (1.8-9.3)	0.7 (0.6-0.9)
Platelets < 100K	Composite	2.0 (1.3-3.1)	0.9 (0.9-1.0)
AST > 70 IU/mL	Composite	1.1 (0.7-1.6)	0.9 (0.5-1.8)

- Blood pressure and other markers fail to reliably predict adverse outcomes
- Providers need tests they can trust

¹ Ukah, U, et al. *Pregnancy Hypertension* 11, Jan 2018;115-123.

The Status Quo: the definition of preeclampsia is proble

- Not based on pathophysiology
- Purely clinical diagnosis; no available biomarkers
- Criteria for diagnosis are unreliable
 - Signs or symptoms that might predict or indicate morbidity
 - i.e. hypertension or pulmonary edema
 - Common and nonspecific
 - i.e. headache; white coat htn
 - Arbitrarily defined
 - i.e. creatinine >1.1 or AST > 70
 - Highly variable and non-sequential
 - i.e. seizure, then hypertension, then low platelets
 - Do not include fetal or placental factors



Diagnostic Unci

Over-use of Re
Latrogenic Preteri
Missed Opportunity
Medico-lega

At UCSD, 30% of pregnancies were evaluated for suspected preeclampsia

- 2402 deliveries at UCSD (2009)
- 725 (30%) had lab test(s) for preeclampsia
 - 406 (56%) tested more than once
 - 146 (20%) ultimately diagnosed with PE
 - 75 (46%) severe PE
 - 654 (90%) had a urine P/C ratio
 - 336 (51%) had repeat assays
 - 159 (22%) had a 24-hour urine
 - 48 (30%) had repeat collection



UCSD Medical Center
La Jolla, CA

New criteria for hypertension and increased prevalence factors will increase number of preeclampsia suspected

2017 ACA/AHA Redefinition of Hypertension

Blood Pressure Categories

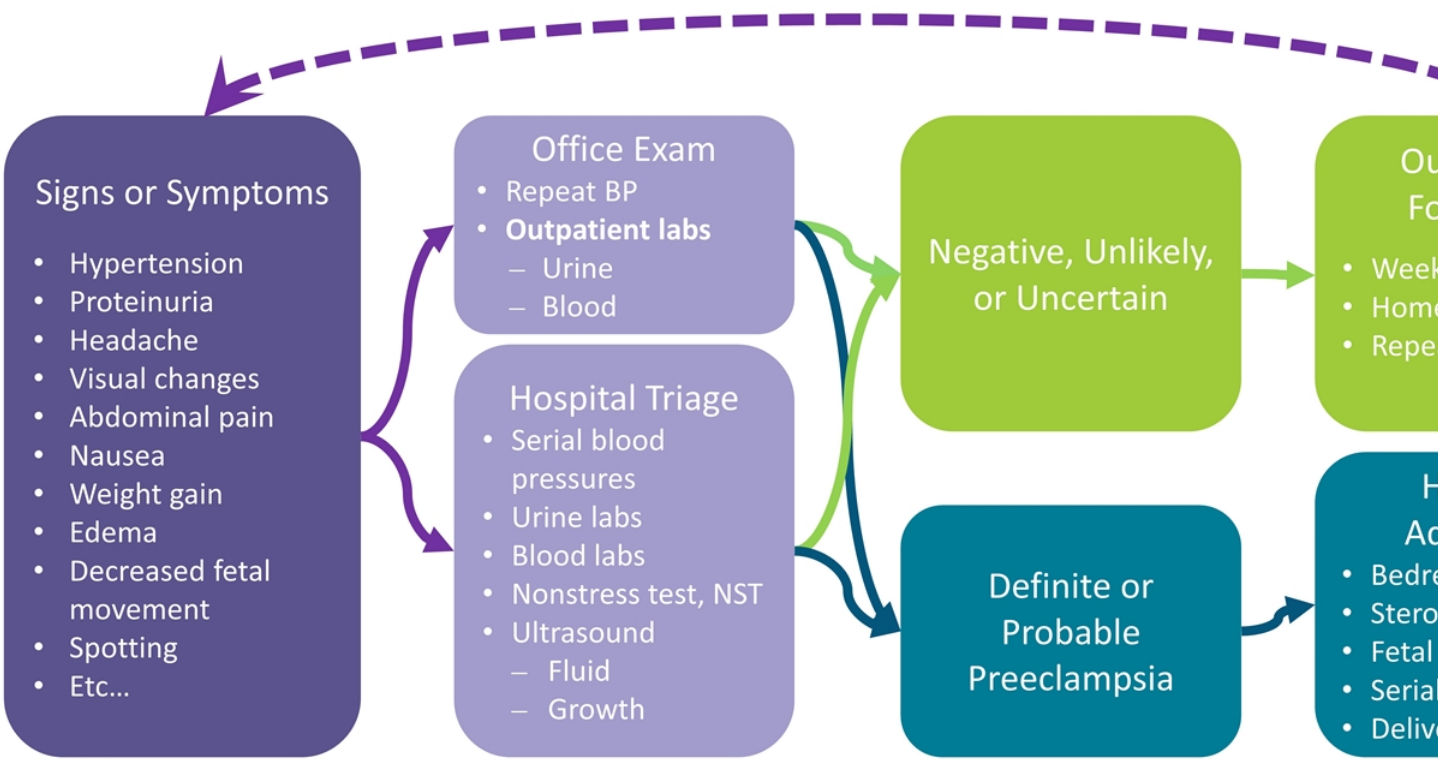


BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 – 139	or	80 – 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

BP category, prevalence and among pregnant women

BP Category	Prevalence
Normal	71.7%
Elevated BP	14.1%
Stage 1 HTN	7.4%
Stage 2 HTN	6.8%

The evaluation of suspected preeclampsia is cumbersome



Patient Case

- **27 y.o. 1st pregnancy, generally healthy**
 - Early blood pressure 127/82, overweight, family history diabetes
- **34 weeks blood pressure 144/85, repeat 136/82**
 - Urine 1+ protein
 - Reports headaches, occasional visual floaters, swelling of legs and feet, post meal abdominal pain
- **Sent to hospital. First 2 BPs >140/90, but mostly normal after rest**
 - Urine P/C ratio 0.34 (positive); urinalysis contaminated – possible infection
 - Normal Cr, Platelets
 - High LFT's (ALT 65, AST 54). Concern for liver disease
- **Admitted to observation and studies**
 - Fetal US, Abdominal US (fatty liver), Serial labs (only LFT's high)
 - 24-hour protein 218 gm (normal), Urine culture is positive (treated for UTI)
 - Discharged home after 36 hours.

There is a significant clinical unmet need to assist in the of preeclampsia

- Biomarkers of preeclampsia

- High specificity and PPV

- Assist confirmation of clinical diagnosis
 - Stratify risk for delivery or severe phenotype

- High sensitivity and NPV

- Assist exclusion of diagnosis
 - Provide confidence that pregnancy may continue
 - Reduce unnecessary hospitalization and intervention
 - Reduce frequency and intensity of ancillary laboratory follow up
 - Improve prediction of latency until onset disease or delivery

Summary

- Preeclampsia presents in many ways and is difficult to diagnose
 - Overlooking mild signs may lead to missed diagnosis and adverse outcomes
 - Overreacting to mild signs may lead to unnecessary intervention
- Providers (MDs and midwives) need accurate, reliable diagnostics to modernize their approach to evaluation
 - While high specificity is helpful for rare cases, high sensitivity is more useful in everyday situations to simplify triage of healthy women
 - Similar to cardiac troponins, a preeclampsia test that rules out severe or impending disease would be a breakthrough advancement in women's healthcare



Preeclampsia cost of illness study

Maternal & infant costs

Mathew Cooper, PhD, MBA
Chief Scientific Officer

Maternal & Infant Health Care Costs Related to Pree

- Objective: Determine PE maternal + fetal cost estimates compared to uncomplicated and hypertensive pregnancies using US primary case data
- Data collected retrospectively from Geisinger Healthcare system
 - Healthcare outcomes and actual billing/payment amounts
 - Note: research sponsored by Progenity
- Figures in 2015 US dollars (add 8.5% to get 2020 dollars)
- Cohorts normalized to 712 mother/baby matches per cohort
 - Matched cohort design; costs more attributed to incremental PE costs
 - Costs independent of maternal & gestational age, BMI, medical care utilization, etc.

Methods Overview

- US, maternal + fetal costs, payer perspective, from 2010-2015
- Compared PE to hypertensive and uncomplicated cohorts
 - Equivalence using maternal age, parity, BMI, comorbidities
- Mothers of singleton pregnancies only
- Costs GA 20 weeks to 6 weeks post delivery maternal
 - Birth to 12 months for infant
- Study used EMR data to link mother/infant pairs
 - Captures healthcare outcomes and actual (not imputed) costs
 - No self-reported data



Cohort Normalization

focus on incremental PE costs

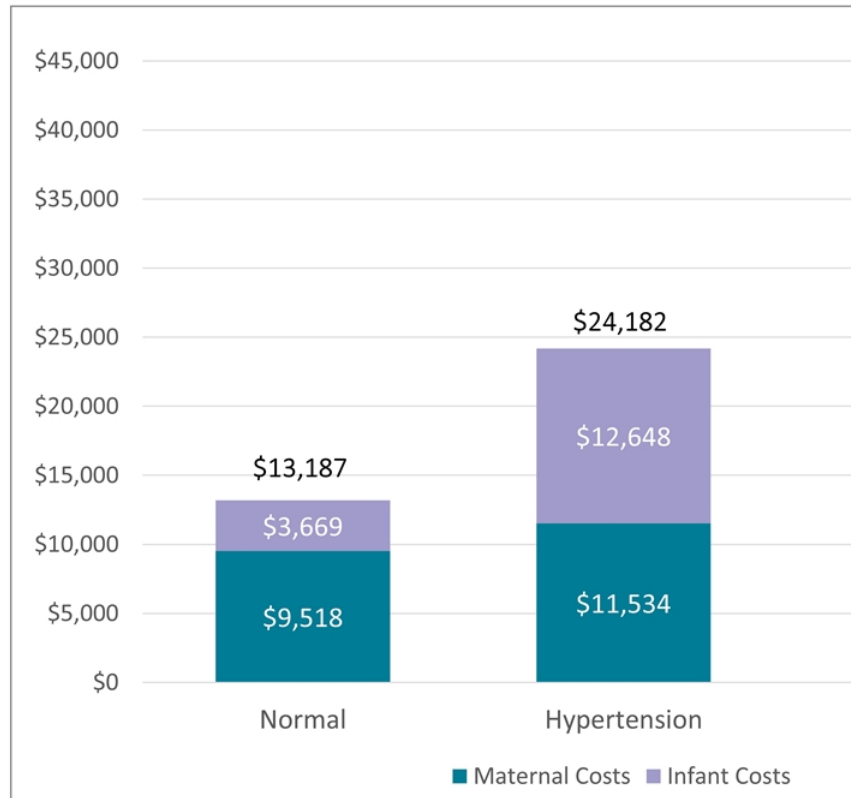
	Uncomplicated (n=712)	Hypertension (n=712)	Preeclampsia (n=712)	d (Between Uncomplicated and Preeclampsia)	H Prec
Age (y)	26±6	27±6	27±6		
Younger than 20	75 (10.5)	75 (10.5)	75 (10.5)	0	
20–34	561 (78.8)	561 (78.8)	561 (78.8)	0	
35 or older	76 (10.7)	76 (10.7)	76 (10.7)	0	
Race					
White	686 (96.4)	651 (91.4)	661 (92.8)	0.16	
1st pregnancy	398 (55.9)	398 (55.9)	398 (55.9)	0	
BMI (kg/m ²)					
Less than 30	357 (50.1)	357 (50.1)	357 (50.1)	0	
30 or higher	355 (49.9)	355 (49.9)	355 (49.9)	0	
Comorbidities [†]					
CCI score	0.15±0.39	0.16±0.43	0.15±0.39	0	

Pulled from patient pop of uncomplicated = 4,210; hypertension = 1,005; PE = 736

Results: maternal and infant costs by cohort

Total incremental costs

- **\$28,603**
(\$3,374 for mothers and \$25,229 for infants) vs. normal cohort
- **\$17,608**
(\$1,358 for mothers and \$16,250 for infants) vs. hypertension cohort



Key Clinical Findings

- Average gestational age (wks) at delivery lowest in PE
 - Uncomplicated (40), hypertensive (38.7), **PE (36.5)**
- Cesarean delivery (%) highest in PE
 - Uncomplicated (29.6), hypertensive (38.3), **PE (50.0)**
- LOS (days) highest for mothers/**infants** highest in PE
 - Uncomplicated (2.2/**2.1**), hypertensive (3.1/**4.8**), **PE (4.8/9.8)**
- No significant difference in mortality
 - Uncomplicated (0.3%), hypertension (0.8%), **PE (0.7%)**



Preeclampsia presents a High Cost Burden in L

- Preeclamptic pregnancies represent an estimated total cost of \$8.6-13.8B¹
 - Based on 2019 birth rate², PE incidence rate of 5-8%³, avg total cost per case \$45,890⁴
- Estimated incremental cost of \$5.4-8.6B¹
 - Based on 2019 birth rate², PE incidence rate of 5-8%³, avg total cost per case \$31,409⁴

Births Nationally (2019)	3,745,540			
Preeclampsia Incidence			Low Estimate	High Estimate
			5%	8%
Total Patients	2015 dollars	2020 dollars	187,277	299,643
Total Cost	\$ 41,790	\$ 45,890	\$ 8,594,066,432	\$ 13,750,506,291
Incremental Cost	\$ 28,603	\$ 31,409	\$ 5,882,174,734	\$ 9,411,479,575

- These are underestimates since above is only payer perspective
 - Estimates do not include direct medical costs incurred outside this representative heal non-direct medical costs, direct non-medical costs, or longer-term costs

1. Estimates derived from applying known, direct costs from a representative healthcare system to US national stats; 2. <https://www.cdc.gov/nchs/data/vsrr/vsrr-8-508.pdf>; 3. Pree Gynecol. 2019 Dec;134(6):1227-1233 adjusted to 2020 dollars

Items to Note

- One healthcare system, not a national estimate
 - Geography, race known confounders
- Payer perspective limits cost burden to direct medical care costs
 - Not a comprehensive societal perspective, which would include additional components (direct nonmedical and indirect costs) and a longer time horizon; maternal/infant adverse outcomes
- Medical cost estimates do not capture medical care services provided outside the single integrated health care system

Acknowledgements and additional information

- **Geisinger Study Team**

- Susan R. Snyder, PhD; Principal Investigator
- Jing Hao, PhD, MD; Co-Investigator
- Jove Graham, PhD, Co-Investigator
- Michael Paglia, MD, PhD; Co-Investigator
- Dina Hassen, MPP; Economic Research Analyst
- Qiang Hao, MS, PhD Candidate; Intern
- Jason Brown, MS; Senior Data Analyst
- Victoria Schlieder, MS; Project Manager

- **Sponsor: Progenity, Inc.**

- **Presentations**

- Posters: International Society of Pharmacoeconomics and Outcomes (ISPOR), 5/2018; AcademyHealth Society for Maternal and Fetal Medicine (ASPM), 2/2019
- Manuscript: Obstetrics & Gynecology (Journal), December 2019

- **Preeclampsia reference source**

- NIH Genetics Home Reference: <https://ghr.nlm.nih.gov/condition/preeclampsia#genes>

Preecludia™ | The development journey from bench to bedside.

Pankaj Oberoi, PhD

Vice President Research & Development, Progenity

Clinical care path for preeclampsia

~20% of pregnant women will experience signs & symptoms of preeclampsia¹.
 ~ 5% are clinically diagnosed²



ACOG Guidelines provide clinical criteria for preeclampsia, but equivocal findings are c



- Signs**
- Blood pressure $\geq 140/90$ mmHg
 - Proteinuria ≥ 300 mg/dL per 24 hrs
 - Protein: Creatinine Ratio > 0.3
 - Impaired liver function
 - Thrombocytopenia
 - Renal insufficiency
 - Pulmonary edema

- Symptoms**
- Headache
 - Abdominal pain
 - Shortness of breath
 - Generalized swelling
 - Complaints of "I just don't feel right"



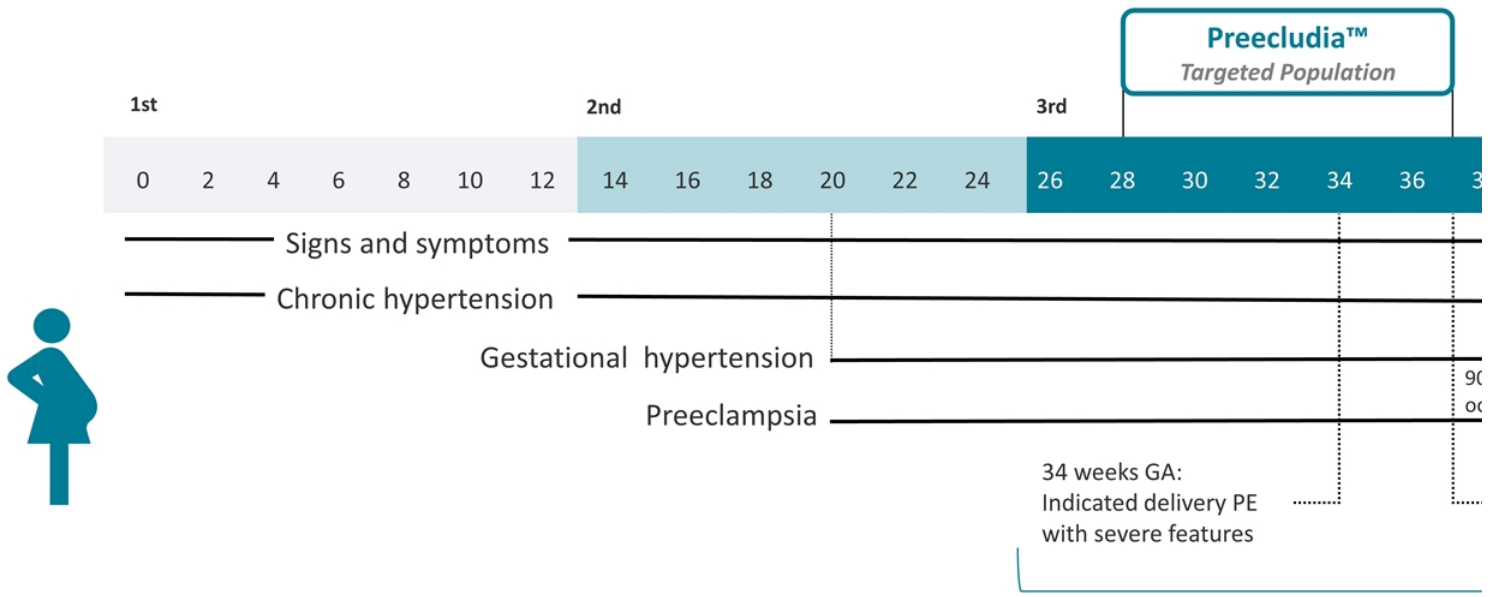
Diagnosis of Preeclampsia

Follow established management guidelines

- Equivocal Clinical Findings**
- Signs and symptoms are not sufficiently diagnostic for preeclampsia
 - Uncertainty leads to potentially unnecessary interventions
 - Changes in clinical management
 - Increased monitoring and testing
 - Iatrogenic intervention, including preterm delivery

1. <https://www.sciencedirect.com/topics/medicine-and-dentistry/gestational-hypertension> Accessed October 10, 2020
 2. <https://www.uptodate.com/contents/preeclampsia-clinical-features-and-diagnosis>

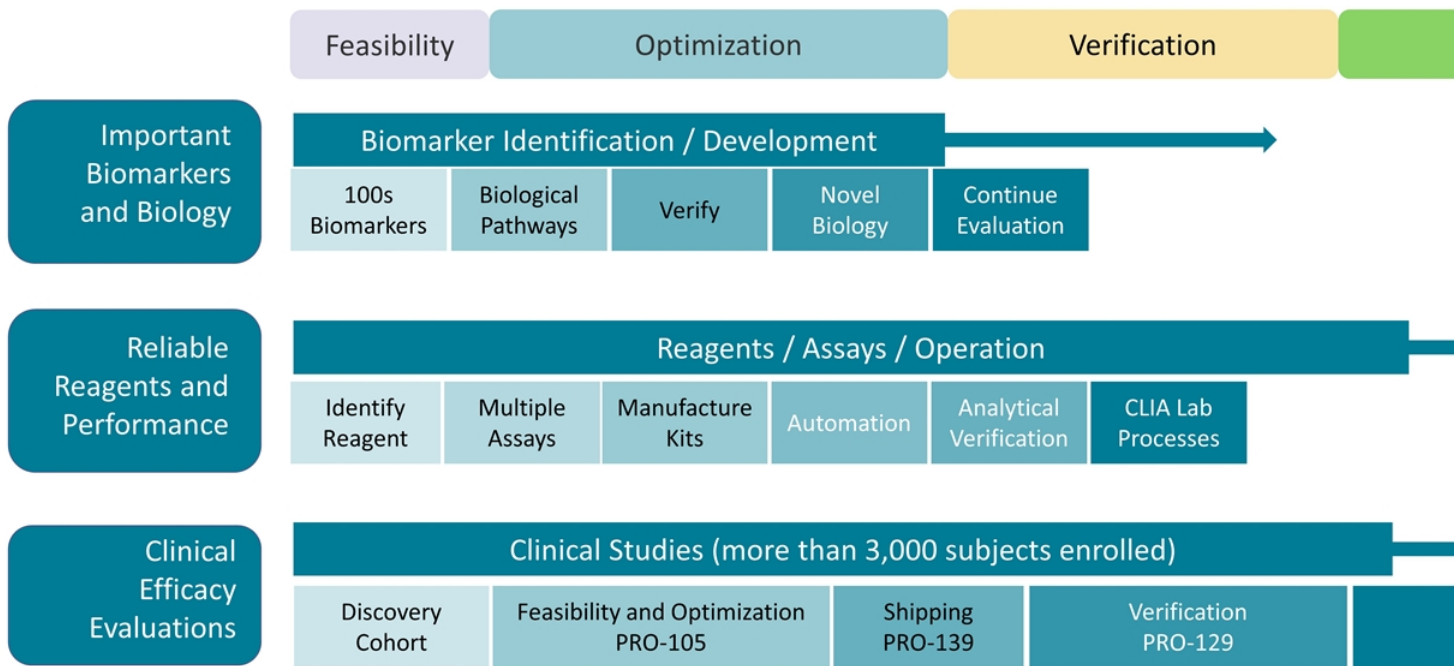
Overlapping symptomology within the target patient po



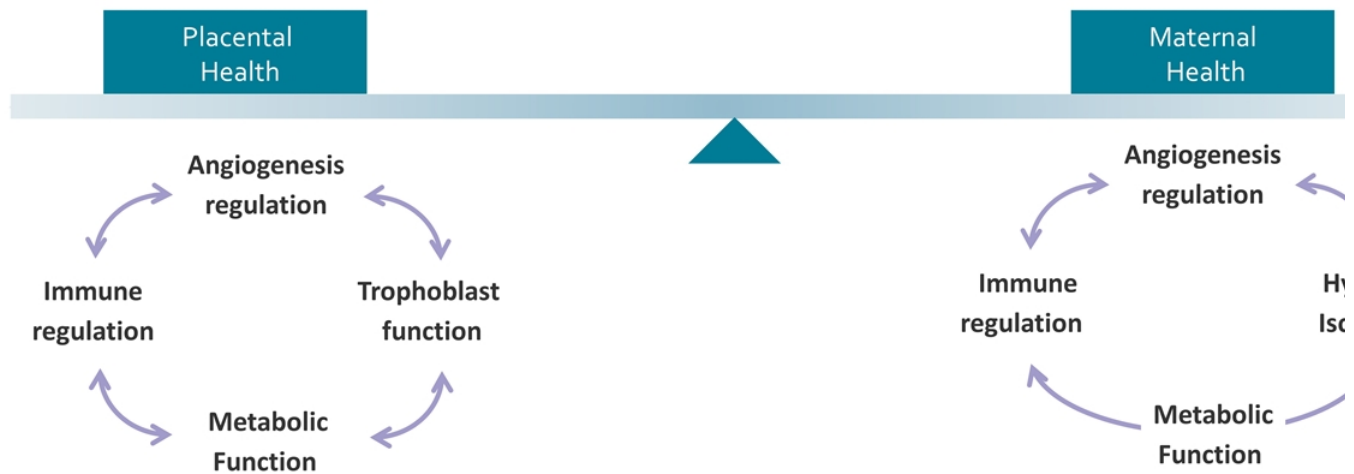
ACOG Management Guid

- <https://www.sciencedirect.com/topics/medicine-and-dentistry/gestational-hypertension> Accessed October 10, 2020
- <https://www.uptodate.com/contents/preeclampsia-beyond-the-basics>. Accessed October 10, 2020
- The American College of Obstetrics and Gynecologists (ACOG). Task force – ACOG Guidelines: Hypertension in Pregnancy. *Obstet Gynecol.* 2013;122(5):1122-31.
- The American College of Obstetrics and Gynecologists (ACOG). ACOG Practice Bulletin No. 202: Gestational Hypertension and Preeclampsia, *Obstetrics & Gynecology*: 2019 - Volume 133 - Issue 1 - p e1-e25.

Preecludia™ product development process using our platform



Eight biomarkers used to help assess placental & matern

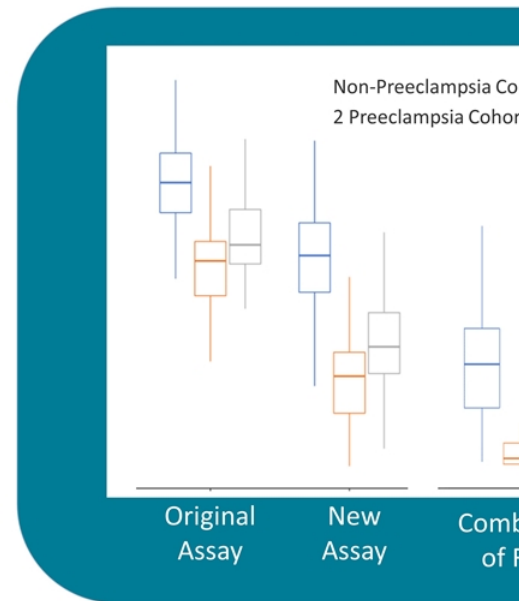


- Poor invasion of trophoblasts
- Intrauterine growth restriction
- Poor metabolic health of placenta
- Oxidative stress of placenta

- Hypertension
- Inadequate perfusion to blood rich organs
- Endothelial dysfunction
- Sudden onset edema
- Gestational hypertension
- Liver/kidney dysfunction
- Heightened immune response
- Proteinuria

Using multiple forms of a biomarker improved test performance

- **Clinical samples** identified improvement to biomarker assay.
- **Increased robustness** to different patient populations
- **Novel form** of biomarker
- **Improved test** performance with combination of biomarker forms.
- **Biologically relevant** for placental health
- Extensive and developing **Intellectual Property** portfolio



Assay Type	Performance Metric
Original Assay	
Improved Assay	
Combination of Forms	

Performance on a subset of samples from

Preecludia analytical verification achieved

- Achieved acceptance criteria for CAP Validation Test Performance Specifications
- Complete accuracy, precision, sensitivity on multiple lots of reagents.
- Verified linearity, interference, specificity, stability and reference ranges.
- Confidence that clinical studies reflect biological responses associated with Preeclampsia

Representative Data from Four Assays Comprising the Pree

	Assay 1		Assay 2		Ass
	Conc.	%CV	Conc.	%CV	Conc.
Sample A	416	3.9	2679	3.9	23931
Sample B	309	4.6	1939	4.2	16573
Sample C	446	3.1	4386	4.5	10772
Sample D	554	4.1	2837	4.7	8146
Sample E	470	3.7	3003	5.0	39308
Sample F	337	3.4	6792	4.4	29571
Sample G	3318	2.8	672	4.6	4726
Sample H	155	5.4	950	3.5	2166

Representative data from samples measured across 16 runs durin



Feasibility and optimization results: PRO-105

Training (>900 Subjects)

- Positive subjects with a diagnosis of preeclampsia
- Negative subjects do not have preeclampsia

Optimization Test

- Only subjects from intended use population
- Women with signs and symptoms
- Healthy subjects *not* used
- “Clinical evidence” to measure performance:
 - Independent adjudicators
 - Medically indicated pre-term delivery

LDT Optimization Performance

Sensitivity	Specificity
91.0% [78.1 – 96.5]	79.9 [75.0 – 84.1]

NPV calculated at a 10% prevalence representing for the test

Verification Study (PRO-129)

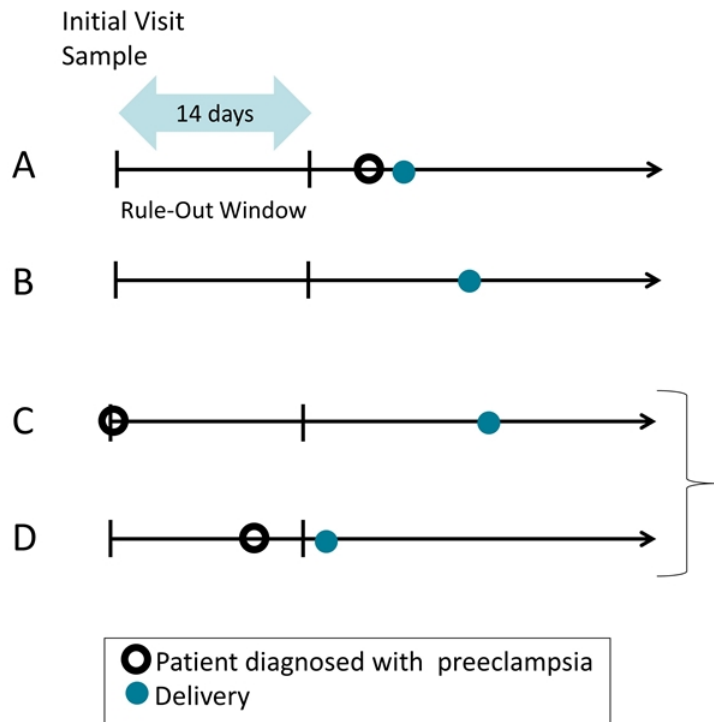
Enrolled Pregnant Women from 24 U.S. Sites

- > 400 Subject enrolled; prospective; blinded
- 17 OBGYN; 7 MFM
- 18 to 45 years of age
- Gestational 28 0/7 to 36 6/7 weeks'
- Subjects collected presented with:
 - Signs and symptoms of preeclampsia.
 - Conditions contributing to the suspicion of a diagnosis of preeclampsia.
- Multiple races and ethnicities

Independent Adjudication of C

- Process to ensure uniformity in the of patients across clinical sites
- 2-3 Independent Clinicians (Maternal Medicine specialists) adjudicated based on the 2013/2019 ACOG Guidelines
- All central adjudicators were required agreement on diagnosis of Preeclampsia
- Followed subjects longitudinally to evaluate rule out window

Window for ruling out risk of preeclampsia



Status: Negative

Expected "negative" result when there is no diagnosis is within 14-days of the sample/initial visit.

Status: "At Risk"

Expected "at risk" result when the diagnosis is within 14-days of the sample/initial visit.

Performance of our test with the **Clinical Verification** study

- Evaluated **locked algorithm** from feasibility with the same cutoffs
- Optimization performance replicated on **independent patient cohorts**
- Observed **high sensitivity** and **high NPV** required to assist with ruling out the risk of preeclampsia
- Established performance for a **14-day rule-out window** in our target patient population

Verification Performance (PR >400 patients enrolled)

	Sensitivity	Specificity
Preeclampsia Performance	88.0% [76.2% – 94.4%]	73.3% [68.1% – 78.0%]

* NPV calculated at a 10% prevalence representing the expected prevalence in the target population

Next phase: Clinical Validation Study (PRO-104)

Clinical Validation Stud

Clinical Study	Objective
✓ PRO-105	Develop algorithm (Training and Test sets)
✓ PRO-139	Shipping and stability studies
✓ PRO-129	Verification
☐ PRO-104	Validation

- >1,700 Subjects (>3,000 samples)
- Blinded, prospective, multi-center
- 21 Geographically diverse U.S. sites (L&D)
- Samples have been collected and tested starting Q1 2021.
- Adjudication of clinical diagnosis by three independent MFMs based on guidelines
- Clinical data and sample IDs are blinded to development group
- Complete Clinical Validation phase by Q3 2021.

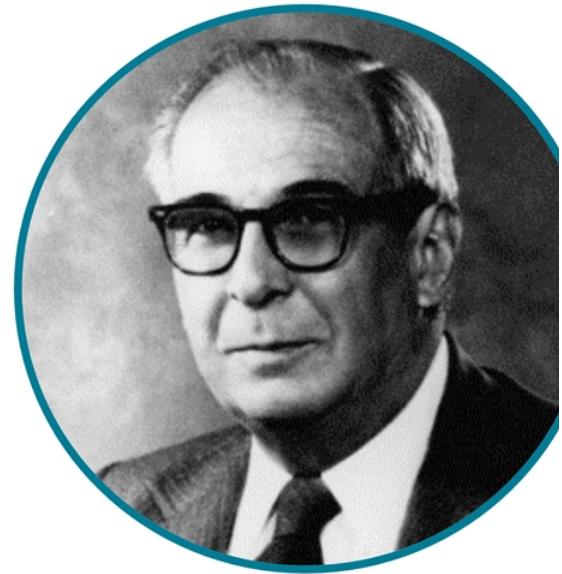
Preeclampsia: The gravity of the condition and the unmet need in assessment

Christopher Robinson, MD, MSCR, FACOG

Partner, Charleston Maternal Fetal Medicine

Preeclampsia – the great obstetrical syndrome

- Proteinuria – Lever/Simpson 1843
- “Father of Preeclampsia Investigation”
- Recognized the “spectrum of preeclampsia”

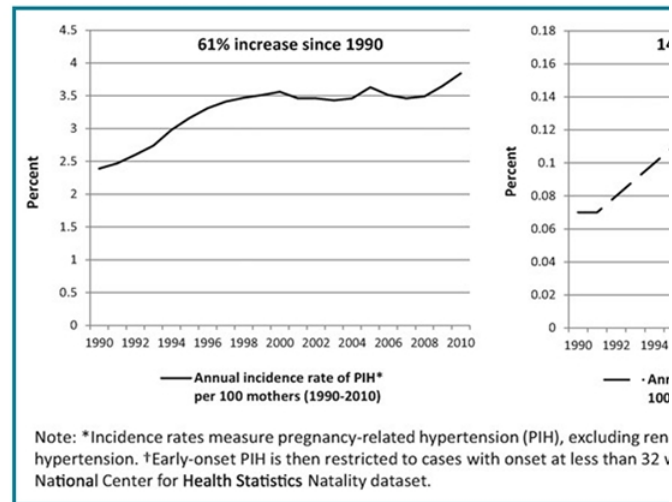


Leon C. Chesley, Ph.D.
1908-2000

Preeclampsia: one of the unsolved “obstetric syndromes”

Preeclampsia

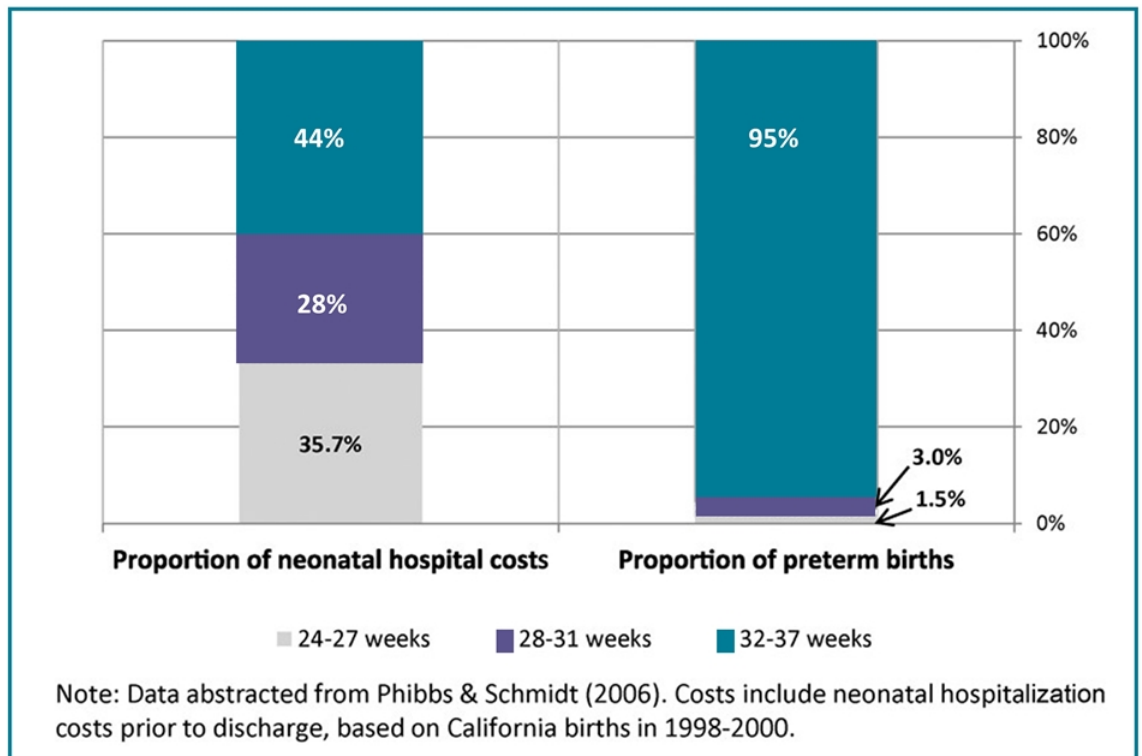
- Currently treated with delivery of the baby
- Lacks warning signs that can be detected prior to onset of the maternal symptoms. Limits prognostication of course and severity of the disease
- Risk groups exist and allow for monitoring for onset of disease.
- Accuracy of diagnosis limited given current diagnostic tools are not linked directly to biologic presentation of disease



Martin JA, Osterman MJ. Describing the increase in preterm births in the United States, 2014–2016. NCHS Data Brief, no 312. Hyattsville, MD: National Center for Health Statistics. 2018. National Center for Health Statistics, final natality data. Retrieved November 03, 2020, from www.marchofdimes.org/peristats.

45 Phibbs CS, Schmitt SK. Estimates of the cost and length of stay changes that can be attributed to one-week increases in gestational age for premature infants. Early Hum Dev 2006; 82 (2) 85-95

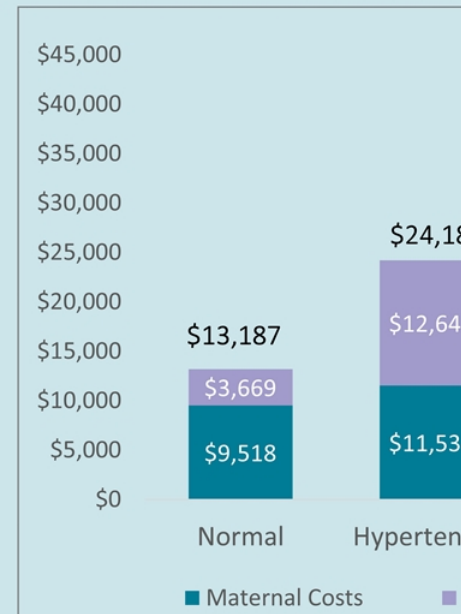
Distribution of neonatal hospital costs versus incidence birth in the United States for all births, by gestational age



Improving gestational age at delivery is primary to improved outcomes for pregnancy and cost

- Preeclampsia is associated with a lower gestational age at birth by ~2-3 weeks gestation and higher NICU costs
- Preeclampsia is associated with greater long-term costs to mothers and infants not captured in these costs estimates
- Total incremental cost to U.S. Health System due to preeclampsia:
 - \$1.2 billion for maternal care
 - \$8.2 billion for infant care

Preeclampsia was estimated to cost the US health care system an increment above the usual maternal and infant care associated with



Obstet Gynecol. 2019 Dec;134(6):1227-1233
*\$28,607 incremental PE cost x 8% incidence

Despite the increasing rates of preeclampsia

- 1 There have been no advances in diagnostic assessment
- 2 There have been no improvements in triage of patients with suspected preeclampsia

Preeclampsia: ACOG diagnostic criteria

Blood Pressure

Systolic blood pressure of 140 mm Hg or more or diastolic blood pressure of 90 mm Hg or more on two occasions at least 4 hours apart after 20 weeks of gestation in a woman with a previously normal blood pressure

Systolic blood pressure of 160 mm Hg or more or diastolic blood pressure of 110 mm Hg or more. (Severe hypertension can be confirmed within a short interval (minutes) to facilitate timely antihypertensive therapy).



Proteinuria

300 mg or more per 24-hour urine collection (or this amount excreted from a timed collection)

OR

Protein/creatinine ratio of 0.3

OR

Dipstick reading of 2+ (used only if quantitative methods not available)

The Variability of Proteinuria in the Hypertensive Complication of Pregnancy by Leon C. Chesley

(From the Department of Biochemistry, Margaret Hague Maternity Hospital, Jersey City, N. J.)
(Received for publication July 10, 1939)

Proteinuria in eclampsia was first described by Lever (1) in 1843, and since that time has been interpreted by many writers as a sign of a renal lesion underlying the toxemias of pregnancy. In



In contrast to the nearly constant protein filtration in each individual in the two groups of nephritics, there is marked variation from hour to hour among the eclamptic and preeclamptic patients. In one eclamptic the protein concentra-



In toxemia of pregnancy, the protein filtration is variable. It is suggested that this argues for a functional cause (vascular spasms) for the proteinuria.

Common presentations often lead to preeclampsia eval the obstetric triage dilemma

- Patient presents for triage for obstetrical problem. Often, these are false labc pregnancy related complaints
- Initial nursing triage would include assessment of chief complaint, collection and measurement of blood pressure.
- Blood pressure returns and is 140/92.
- Fetus is placed on electronic fetal monitoring
- Urine is assessed for protein (usually P/C ratio but also dipstick)

Current Preeclampsia definitions and their relationship with outcomes are incomplete

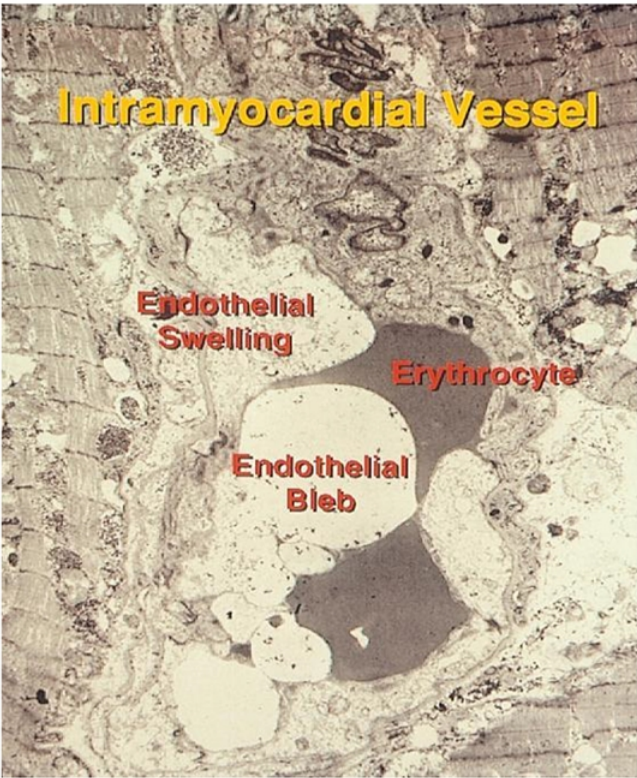
Detection rate of adverse pregnancy outcomes according to different definitions of preeclampsia

	Traditional (n=281)	Ref	ACOG (n=326)	p value	ISSHP-M (n=338)	p value	ISSHP-MF (n=434)	p value	ISSHP
Detection rate (% (n/N))									
Severe maternal hypertension	40.6 (52/128)	-	46.1 (59/128)	0.449	56.2 (73/130)	0.013	59.2 (77/130)	0.004	(8)
Major maternal morbidity	72.2 (13/18)	-	100 (18/18)	0.046	100 (18/18)	0.046	100 (18/18)	0.046	(1)
Perinatal mortality and major morbidity	46.9 (38/81)	-	49.4 (40/81)	0.875	59.8 (49/82)	0.117	62.2 (51/82)	0.060	(1)
Neonatal unit admission ≥48 hr	51.4 (54/105)	-	53.3 (56/105)	0.890	60.7 (65/107)	0.213	64.5 (69/107)	0.070	(8)
Birthweight <10 th percentile	40.5 (60/148)	-	46.3 (69/149)	0.349	51.3 (77/150)	0.064	70.1 (108/154)	<0.0001	(1)

The p value represents the comparison of the detection rate with the traditional definition of preeclampsia.

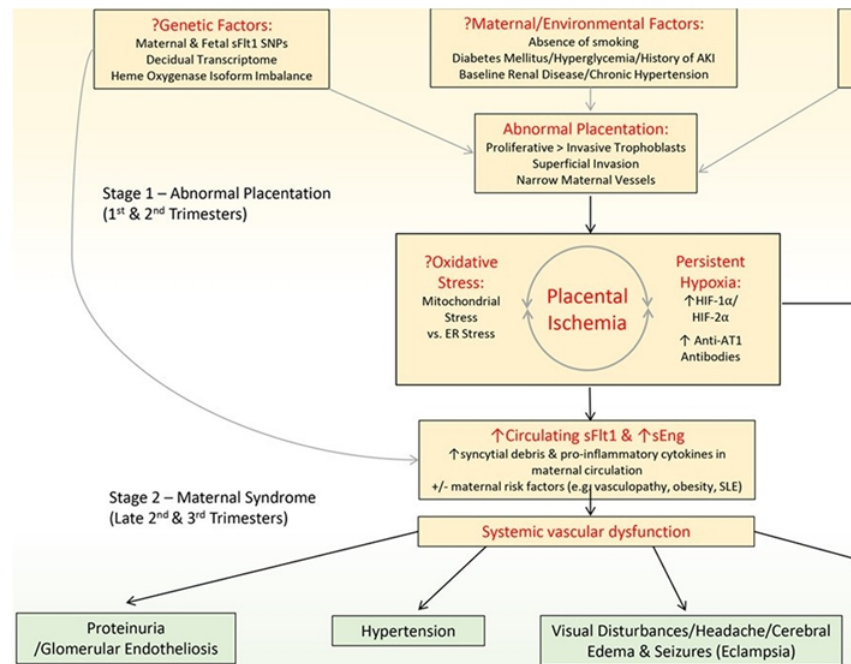
Additional precision is needed – biomarkers of disease activity / severity

Preeclampsia: more than just hypertension . . .



The origins of preeclampsia are multifactorial and are derived from multiple biologic pathways

A better assessment of preeclampsia will start with inclusion of biomarkers from the pathways involved in the development and progression of the disease state and severity.



Sarosh Rana. Circulation Research. Preeclampsia, Volume: 124, Issue: 7, 2019, Pages: 1094-1112, DOI: (10.1161/CIRCRESAHA.118.313276)
 Nalajayan, M.V., & Karumanchi, S. (2013). New developments in the pathogenesis of preeclampsia. *Advances in chronic kidney disease*, 20 3, 265-70 .

Preeclampsia: more than hypertension . . .

Current Triage Assessment

- Blood pressure
- Protein assessment in urine
- Lab Assessments

**This approach misses 50% of
adverse neonatal outcomes**

Ideal Triage Assessment

- Blood pressure
- Protein assessment in urine
- Lab Assessments

AND

**Biomarkers of Disease Involved
in Pathophysiology**

The current vs. ideal triage of the suspected preeclampsia

Current Triage

- Assessment of Blood pressure and Protein
- Steroids (in case PE is present)
- Magnesium (in case PE is present)
- Inpatient admission (until course of disease is determined) – Possible delivery if worsens
- Outpatient follow-up twice per week with fetal testing and labs ongoing until 37 weeks when delivery is planned

Ideal Triage with a Rule-c

- Assessment of Blood pressure and Protein
- Biomarker Triage test with “rule out” preeclampsia

PE Ruled Out
(High Sensitivity &)

Routine Care for
duration of ruled out
period (~ 2 weeks)

PE N

Con
ongoing
Mana

Patient Triage Typical Case Scenario

- Patient in triage for obstetrical complaint with blood pressure elevated at 140/90 mmHg. Patient is placed on electronic fetal monitoring and testing is reassuring. Urine is noted to have 1+ protein.
- Clinician Dilemma: Admit to hospital for ongoing care or manage in outpatient? Is preeclampsia present? Is patient at risk?
- **Without a Biomarker Test:** We lack precision of diagnosis and this leads to over and under diagnosis due to clinical variation.
- **With a Biomarker Test:** An objective measure of disease activity has the potential to greater precision and accuracy of diagnosis and prevent unnecessary preterm hospitalization and intensity of medical intervention (serial labs, steroids, magnesium).

What do clinicians need in the management and triage patients with symptoms suspected of preeclampsia?

- 1 A test that is based in the pathophysiology of preeclampsia
- 2 Rapid ability to rule out disease and thereby prevent unnecessary interventions, hospitalizations and cost.
- 3 Ability to notify patient of risk or lack of risk in pregnancy during triage
- 4 Ability to prevent unnecessary delivery of pregnancy when preeclampsia
- 5 Increased confidence in performance of testing for preeclampsia.

Summary: Improving outcomes requires accuracy in assessment of preeclampsia risk

- The incidence of preeclampsia is increasing
- There is no effective cure for preeclampsia – delivery always remains the treatment of choice
- Current diagnostic testing for preeclampsia lacks a direct relationship to the biological pathways involved in disease leading to missed opportunities in diagnostic accuracy
- Improved diagnostic assessment will lead to improved outcomes through targeted decisions for delivery in pregnancy at risk.

Preecludia™ | Clinical Evidence Development

Christina Settler, MS, CGC

Vice President of Medical Affairs, Progenity

Progenity Preeclampsia Clinical Program Overview

IRB approved observational clinical studies executed according to GCP

Studies conducted over a 6-year period

54 Independent U.S. Clinical Sites used across all studies

OB-GYN ↔ **MFM**

Routine Care

Refer Complex and PE cases to MFMs



Specialized Care

Influence OB/GYN decision making



Patients in Intended Use Pop
Managed by All Types of Cl

Clinical Study Portfolio

Completed Studies

Clinical Study	Application	Number of patients enrolled
PRO-105	Biology/Feasibility	>1,300
PRO-129	Verification	>450
PRO-104	Validation	>1,800
PRO-139	Stability/Shipping	150



A total of > 3, enrolled to da support the d of Preecludia¹

Future Studies

Clinical Study	Application	Intended number of patients enrolled
PRO-136	Expands Intended Use	1,000
PRO-142	Clinical Experience	1,500
PRO-140	Clinical Utility	>1,700



A total of > 4, patients are e be enrolled to Preecludia™ p

Planned publications & Future PE clinical program Sumr

- **Planned publications**

- Clinical verification data
- Clinical validation data
- Meta analysis combining verification and validation data
- Preeclampsia disease biology and pathophysiology

- **PRO-136:** Observational Clinical Study; acquire clinical samples to enable **exp target patient population**; study in the Start-Up Phase Q4 2020

- **PRO-142:** Observational Clinical Study; assess initial **user experience** of the Pr PE Test; enrollment targeted to begin Q3 2021

- **PRO-140:** Randomized Controlled Clinical Study; to assess the **Clinical Utility** Progenity PE Test; enrollment targeted to begin Q4 2021 into 2022

Summary

- Progenity has a strong, well-established Clinical Operations Department including
 - Clinical Research coverage of the entire US
 - Data-Management and biostatistics
 - Progenity Biorepository in Ann Arbor
- We have a robust and diverse network of Clinical Researchers / Key Opinion Leaders necessary for the design, execution, and interpretation of our Clinical Studies
- Progenity has conducted multiple studies, enrolling over 7,500 participants to the development of preeclampsia that will help improve the current standard of care

Q&A

Closing Remarks

Harry Stylli, PhD

CEO, Chairman, and Co-founder, Progenity

Preecludia™ - A high Potential Rule Out Test for Preecl

- Established a fundamental understanding of preeclampsia and the great **clinic need** that exists today in assessing patient risk in our channel: Ob/Gyn and MI
- Showed the **incremental healthcare cost burden of \$9B+** associated with man preeclamptic pregnancy and its support for premium reimbursement
- Shared our compelling prospective, blinded clinical verification data from 400 subjects for our Preecludia™ LDT rule-out test achieving **high sensitivity of 88%**, **98.2% NPV*** with a rule out window of up to 14 days
- Provided support for the **clinical utility** of a rule-out test and its place in the cl management care path to help improve standard of care
- Demonstrated our ability to advance our program and our efforts to generate **adoption rates** within our women's health channel towards a \$3B US market

* NPV calculated using a 10% prevalence rate

THANK YOU



**New Test for Triaging Preeclampsia Passes Key Development Milestone:
Progenity Releases Prospective Clinical Verification Data for its Preecludia™ Test**

High sensitivity and high negative predictive value (NPV) observed for ruling out the risk of preeclampsia

SAN DIEGO – November 20, 2020 – **Progenity**, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products in women's health is pleased to announce the company has reported clinical verification data for its Preecludia™ preeclampsia rule-out laboratory-developed test currently in development. With its performance data, including an observed 98.2% NPV, Progenity believes the Preecludia test has the potential to become the first tool of its kind in the United States to help triage possible preeclampsia, a potentially deadly condition for both pregnant mothers and their babies.

Preeclampsia is the second most common cause of maternal mortality, and more than 700,000 women present each year with signs and symptoms of possible preeclampsia. It is characterized as a hypertensive disorder, but it is difficult to differentiate from other hypertensive conditions in pregnancy, making diagnosis and management difficult. Ultimately, left undiagnosed and improperly managed, preeclampsia can result in impaired organ function, seizures, stroke, and death in the mother, and may require pre-term delivery of the baby. This can result in both poor health outcomes and significant costs. The total available U.S. market for a high NPV rule-out test for preeclampsia is forecasted at up to \$3 billion, and there is also a large potential global opportunity.

The Preecludia test is being developed to serve as a potential triage and rule-out test to help providers differentiate between patients with symptoms who are at risk for preeclampsia. This proprietary test is a multi-analyte protein biomarker assay which is designed to be run from a simple blood draw. In the prospective, blinded PRO-129 clinical verification study, samples were collected and analyzed from over 400 pregnant women with substantial diversity, gathered from 24 U.S. clinical sites comprised of predominantly OBGYN and Maternal Fetal Medicine (MFM) practices. Subjects presented with possible signs and symptoms of preeclampsia, including new onset hypertension, but no clear diagnosis. Subject data were independently adjudicated by a third party, and subjects, for whom preeclampsia was not diagnosed at the time of enrollment, were followed longitudinally through delivery. In subjects sampled up to 37 weeks' gestational age, the Preecludia test showed an 88.0% sensitivity, 73.3% specificity, and NPV of 98.2% at a 10% prevalence to rule out a patient's risk of developing preeclampsia within the next 14 days from the date of specimen collection. These data were generally consistent with previous results observed in the test's feasibility and optimization studies.

"The Preecludia test is the first of its kind in the United States designed to help physicians better triage symptomatic patients with suspected preeclampsia," said Harry Stylli, PhD, CEO, chairman, and co-founder of Progenity. "It is tragic that we continue to use 19th century tools to evaluate pregnant women for diseases in the 21st century. We believe there is an obvious unmet need for new and better tools to aid in the triage, diagnosis, and management of preeclampsia. This milestone represents an important step toward our objective to commercialize the Preecludia test in the second half of 2021 and satisfy that unmet need."

Progenity previously announced the successful completion of analytical verification, which evaluated the accuracy, precision, and stability of the test's biomarker assays. The final planned step in the development program is completion of the clinical validation study. The company has already collected over 3,000 samples from more than 1,700 patients enrolled in the PRO-104 validation study, and this study is expected to begin in Q1 2021.

Progenity will provide a thorough review of preeclampsia, its cost to the healthcare system, and the Preecladia test development program during a Preeclampsia R&D Day presentation on November 20, 2020, from 8-10 AM Pacific. For further information or to access the slides presented, please visit: progenity.com/presentations.

About Progenity

Progenity, Inc. is a biotechnology company with an established track record of success in developing and commercializing molecular testing products, as well as innovating in the field of precision medicine. Progenity provides in vitro molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making medical decisions during key life stages. The company applies a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to its molecular testing products and to the development of a suite of investigational ingestible devices designed to provide precise diagnostic sampling and drug delivery solutions. Progenity's vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. For more information on how Progenity is helping clinicians and patients prepare for life, please [visit progenity.com](http://visit.progenity.com).

Forward Looking Statements

This press release contains "forward-looking statements," which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements regarding the development progress of our preeclampsia rule-out test, its future use by providers to rule out preeclampsia, the performance of the rule-out test in an upcoming validation study, the completion of our upcoming validation study, and our efforts and intent to commercialize the Preecladia test and address an unmet medical need. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause the Company's actual results to differ materially from the forward-looking statements expressed or implied in this press release, including the ongoing COVID-19 pandemic and associated shelter-in-place orders, our ability to develop and commercialize our testing products, the size and growth potential of the markets for our products, and our ability to serve those markets, the rate and degree of market acceptance and clinical utility of our products and coverage and rates of reimbursement for our products, the performance of third parties in connection with the commercialization and development of our products, regulatory developments in the United States and foreign countries, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our ability to improve and enhance our products, our plans to research, develop, and commercialize new products, the development, regulatory approval, efficacy, and commercialization of competing

products, the outcome of pending and future investigations and legal proceedings, the loss or retirement of key scientific or management personnel, our ability to develop and maintain our corporate infrastructure, including maintaining effective internal controls, our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others, and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 11, 2020, and other subsequent documents we file with the SEC. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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