HOLOGIC®

TVUS ***and*** fFN

The data supports it. Do you?

RapidfFN®
for the TLi$_{IQ}$® System

TVUS Results

More Subjective Than You Think

Cervical length is a proven tool to assess the risk of preterm birth, but accurate results are variable even in the hands of skilled and well-trained clinicians. A recent analysis of cervical length measurement images from large, multi-center trials showed a high rate of failed images even though these were conducted at academic medical centers and clinicians received special training.[1]

- A follow-up study of cervical length measurement images submitted for review for individual certification showed a significant number (15%) failed to acquire properly measured cervical lengths.[2]
- Measuring cervical length is not as straightforward as many assume.[2]

Study[1]	"Failed" Images
Preterm Prediction Study (MFMU Network)	20%
SCAN Trial (MFMU Network)	15%
NuMOM2b Network	30%
CerviLenz Study	11.5%
PREGNANT Trial	10%

Why is measuring cervical length so challenging?

1. The cervix responds to uterine contractions, and its measurement may change during an ultrasound examination. One study evaluating the cervical length over 30 minutes, showed a mean difference of 11 mm between longest and shortest measurements.[3]

2. It requires readily available ultrasound equipment and trained users.[4]

3. There is a lack of both formal curriculum and evaluation tools.[2]

Using fFN in addition to TVUS dramatically increases preterm labour prediction.

Risk of sPTB in patients with symptoms of preterm labour[5]

	< 7 days
CL < 30 mm	23% risk

= 1 out of 4
will deliver < 7 days

Negative fFN	< 7 days	< 14 days
CL < 30 mm	11%	13%

1 out of 10
will deliver < 7 days

Positive fFN	< 7 days	< 14 days
CL < 30 mm	45%	53%

1 out of 2
will deliver < 7 days

Preterm labor risk prediction is ***improved by 50%*** when fFN is used in conjunction with TVUS.

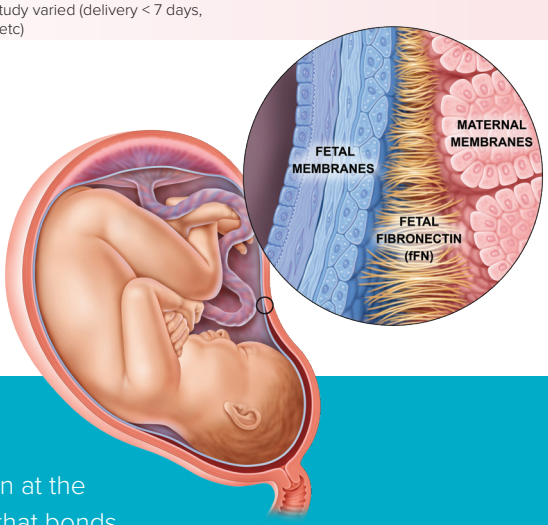
What Is a Short Cervix?

There is no definitive definition of a short or long cervix. Guidelines, protocols and studies have used varying cut-offs for a short cervix which creates difficulties in standardization of the proper length for use during TVUS.[6]

Overview of published studies reporting PTB risk associated with both fFN positivity and short cervix in symptomatic women:

	CL cut-off	Sensitivity	Specificity
Hincz, et al.	21-31 mm	86%	90%
Rozenberg, et al.	≤ 26 mm	55%	82%
Gomez, et al.	< 15 mm, < 30 mm	38%, 53%	89%
Schmitz, et al.	16-30 mm	67%	81%
Eroglu, et al.	< 20 mm, < 25 mm	80%	97%
Ness, et al.	< 20 mm	22%	82%
Asakura, et al.	< 20 mm	62%	71%
Audibert, et al.	< 25 mm	64%	96%
Rose, et al.	16-29 mm, < 15 mm	N/A	

*Note the outcome measures for each study varied (delivery < 7 days, < 14 days, < 34 wks, < 35 wks, < 37 wks, etc)

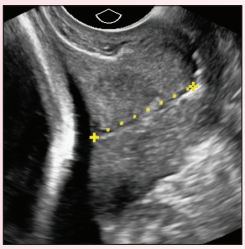


Fetal fibronectin acts as an adhesive glycoprotein at the maternal-fetal interface that bonds maternal membranes to fetal membranes.

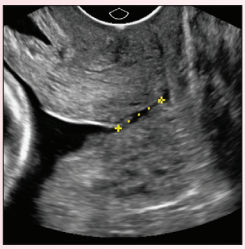
How would each of these TVUS images influence your management?

Patient 1

2.43 cm

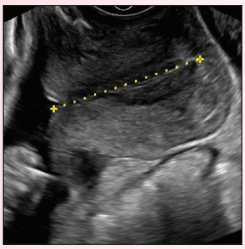


1.21 cm

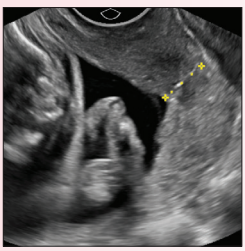


Patient 2

3.88 cm



1.22 cm



Both clinical scenarios demonstrate the variation in cervical length and the potential for changes in management based on the longest and shortest measurements during a single ultrasound evaluation.

20% of Patients Discharged Delivered within 3 days[7]

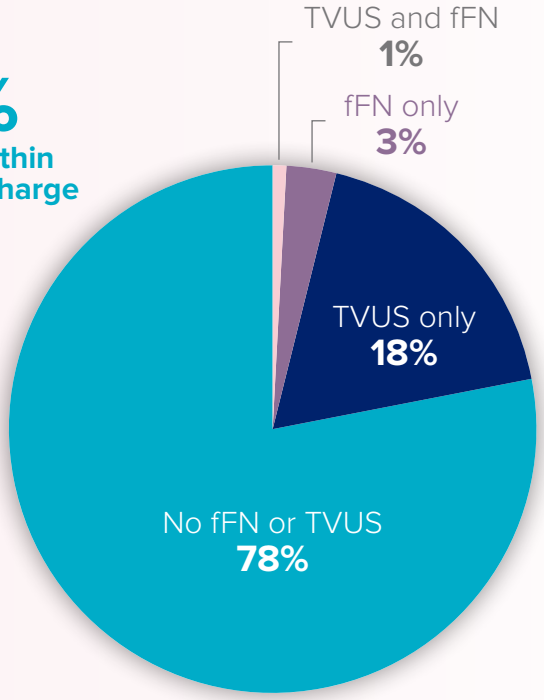
23,062
patients with PTL symptoms

24%
admitted
n = 5,550

76%
discharged home
n = 17,512

80%
delivered > 3 days later
n = 13,995

20%
delivered within 3 days of discharge
n = 3,517



- TVUS and fFN **1%** (n = 41)
- fFN only **3%** (n = 106)
- TVUS only **18%** (n = 620)
- No fFN or TVUS **78%** (n = 2,750)

Underutilized fFN testing and subjective TVUS results led to **missed critical care opportunities**.

References: 1. Perinatal Quality Foundation. CLEAR program. https://clear.perinatalquality.org/wfInformation.aspx. Accessed July 12, 2018. **2.** Boelig RC, Feltovich H, Spitz JL, et al. Assessment of Transvaginal Ultrasound Cervical Length Image Quality. *Obstetrics & Gynecology*. 2017;129(3):536-541. **3.** Meijer-Hoogeveen M, Stoutenbeek P, Visser G HA. Dynamic cervical length changes: Preliminary observations from 30-minute transvaginal ultrasound recordings. *J Maternal-Fetal & Neonatal Medicine*. 2007. 20:6, 481-486. **4.** Parry S and Elovitz MA. Pros and cons of maternal cervical length screening to identify women at risk of spontaneous preterm delivery. *ClinObstetGynecol* 2014; 57(3): 537-46. **5.** R Gomez, et al. Cervicovaginal fibronectin improves the prediction of preterm delivery based on sonographic cervical length in patients with preterm uterine contractions and intact membranes. *AJOG* 2005; 192: 350-359. **6.** DeFranco EA, Lewis DF, Odibo AO. Improving the screening accuracy for preterm labor: is the combination of fetal fibronectin and cervical length in symptomatic patients a useful predictor of preterm birth? A systematic review. *Am J Obstet Gynecol* 2013;208:233.e1-6. **7.** Blackwell SC, Sullivan EM, Petrila AA, et al. Utilization of fetal fibronectin testing and pregnancy outcomes among women with symptoms of preterm labor. *Clinicoecon Outcomes Res*. 2017;9:585-594. doi:10.2147/CEOR.S141061.

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