MAR 12, 2023

OPEN ACCESS

Protocol Citation: Rajamaheswari N, Ilangovan Veerappan, Chandrakala Maran, Harini Sivamani, M. Meena Mahalingam, A. Rajagopal 2023. Efficacy of Simple Urine Test based Machine Learning Screening Software in predicting UTI in pregnancy. **protocols.io** https://protocols.io/view/efficacy-of-simple-urine-test-based-machine-learni-cqkavuse

MANUSCRIPT CITATION: Not Applicable

Protocol status: Working
We use this protocol and it's working

Created: Mar 06, 2023

Last Modified: Mar 12, 2023

PROTOCOL integer ID: 78178

Efficacy of Simple Urine Test based Machine Learning Screening Software in predicting UTI in pregnancy

Rajamaheswari N[1], Ilangovan Veerappan[2], Chandrakala Maran[3], Harini Sivamani[3], M. Meena Mahalingam[4], A. Rajagopal[5]

[1]Urogynaecology Research Centre Pvt.,Ltd , Chennai ,India;
[2]Department of Nephrology, K.G. Hospital and Postgraduate Medical Institute and Research Centre, Coimbatore, Tamil Nadu, India.;
[3]Department of Obstetrics and Gynaecology, K.G. Hospital and Postgraduate Medical Institute and Research Centre, Coimbatore, Tamil Nadu, India.;
[4]Urogynaecology Research Centre Pvt.Ltd, Chennai India;
[5]Indian Statistical Institute, Coimbatore, Tamil Nadu, India

Harini Sivamani

DISCLAIMER

Use of Machine Learning Screening Software (MLSS) at the Point Of Care is at the sole discretion of the user under accepted user policy .
It is complementary to the existing practice and it is not a substitute for any existing protocol.
The authors or affiliated institutions do not take any responsibility for any damages or claims and shall not be responsible or liable for any shortage, discrepancy, damage, loss, destruction or any complications related to the use of this software and cannot be produced as evidence in court of law.
The sale or other disposition of which gives rise to an account involving any financial implications, or for any error, act of omission, or delay of any kind occurring in the use of this MLSS Protocol.

ABSTRACT

Constant vigilance to recognize and treat Urinary Tract Infection(UTI)both asymptomatic & symptomatic bacteriuria throughout pregnancy is necessary as untreated bacteriuria can lead to maternal and fetal complications. Subjecting all pregnant women to routine Simple Urine Tests(SUT)and Conventional Urine Culture Tests(CUCT)to diagnose bacteriuria poses a great challenge in high-volume centers. There is a need to develop a Machine Learning Screening Software(MLSS) as a laboratory protocol to be used as a screening tool in predicting bacteriuria from the results of SUT without subjecting all pregnant women to CUCT unless indicated. Women attending antenatal clinics from February 2020 to January 2021(irrespective of gestational age) were studied for the variables of SUT, CUCT, and patient characteristics. The sample size of 50 was determined with the planning value of bacteriuria at 10 % within a specified 5% margin of error and validated with external data(n=2987). The multivariate diagnostic analytics determined predictors pH, specific gravity(Sp. Gr), and pus cell from SUT variables by calculating eigenvalues(scree plot)and eigenvectors (loading plot). Logistic multiple nominal regression determined 7 significant biomarkers.A combinatorial effect of these biomarkers predicted bacteriuria and classified it, leading to the development of Machine Learning Screening Software(MLSS). Embedding Fuzzy Logic Intelligence Decision Criteria(FLIDC)on MLSS enhanced its accuracy of prediction. MLSS reveals that all pregnant women attending antenatal clinics need not undergo routine CUCT; only 50% would require it. The software identifies pregnant women for whom CUCT is essential. MLSS has 96% accuracy, 85% sensitivity, and 54% specificity. This Point-of-Care screening tool has opened a new simplified pathway to screen all pregnant women for UTI from SUT without subjecting them to CUCT unless indicated. MLSS minimizes the burden of antenatal clinics managing high-volume patients and resource-restricted countries by saving time and resources.

Key words–Pregnancy, UTI, Bacteriuria, Screening software, Fuzzy logic, Point of Care

IMAGE ATTRIBUTION

GUIDELINES

The computational methods are based on the statistical techniques as under:

a) The correlation of significant biomarkers from Simple Urine Test (SUT) is used to predict the probable bacteriurial event.

b) The data mining techniques and machine learning tools analyzed the independent variables as the results of Simple Urine Test(SUT) and dependent variables as the results of the Conventional urine culture test with multivariate prediction analytics

MATERIALS

Results of SUT
Demographic details of pregnant women
Details of patient characteristics
Excel based computer facilities

SAFETY WARNINGS

1. Check your system of data security before using the link.
2. Usage of Machine Learning Screening Software (MLSS) to detect UTI in pregnant women has no adverse impact on the patient as it is only a screening tool that does not involve any intervention.

ETHICS STATEMENT

The study is a prospective, single-arm, observational study conducted from February 2020 to January 2021 by the Department of Obstetrics and Gynaecology of K.G. Hospital and Postgraduate Research Institute, a tertiary care center in Coimbatore. The study was done after obtaining approval from the institutional review board.

BEFORE START INSTRUCTIONS

1. Collection of urine samples of pregnant women following standard laboratory protocol.
2. Standard calibrated measuring devices with provision to do the Simple Urine Test (SUT) which can detect urinary pH, specific gravity, pus cells, albumin, cast, and nitrite conforming to the measurements prescribed in the MLSS.
3. Basic laboratory facility attached to the antenatal clinic of the Obstetrician.
4. Basic excel based computer facility with the availability of the internet to peruse the link provided in the google drive

Efficacy of Simple Urine Test based Machine Learning Scree.

1 What is the scope of Machine Learning Screening Software (MLSS) for Obstetricians?
It is a simple screening tool used to diagnose and monitor bacteriuria throughout pregnancy from the results of the Simple Urine Test(SUT).

2 What is the advantage over present practice?
Machine Learning Screening Software (MLSS) predicts bacteriuria from Simple Urine Test (SUT) consistent with the outcome of the Conventional Urine Culture Test (CUCT) without subjecting to Conventional Urine Culture Test (CUCT) reserving CUCT only for those recommended by

Machine Learning Screening Software (MLSS).
It eliminates the need to subject all pregnant women to routine Conventional Urine Culture Test (CUCT).

3 What is the outcome of this screening software ?
• Prediction of bacteriuria and the probability of bacteriurial events.
• Recommends Conventional Urine Culture Test (CUCT) only for those who require it.

4 What is the basis of computation of this prediction software ?
The correlation of significant biomarkers from the Simple Urine Test (SUT) is used to predict the probable bacteriurial event.
The data mining techniques and machine learning tools analyzed the independent variables of the results of the Simple Urine Test (SUT) and dependent variables of the results of the Conventional urine culture test(CUCT) with multivariate prediction analytics using Minitab version 18.

5 What is the preparation to use 'Machine Learning Screening Software (MLSS)?
• Collection of urine sample from pregnant women following standard laboratory protocol.
• Standard calibrated measuring devices with provision to do the Simple Urine Test (SUT) which can detect urinary pH, specific gravity, pus cells, albumin, cast, and nitrite conforming to the measurements prescribed in the 'Machine Learning Screening Software (MLSS).

6 Explain the safety aspects.
• The usage of 'Machine Learning Screening Software (MLSS) to detect UTI in pregnant women has no adverse impact on the patient as it is only a screening tool that does not involve any intervention.
• Check your system of data security before using the link.

7 What is the infrastructure required before use?
• Basic laboratory facility attached to the antenatal clinic of the Obstetrician.
• Basic excel based computer facility with the availability of the internet to peruse the link provided in the google drive

8 What are the steps to open the link – data1?
Click on the google drive link https://docs.google.com/spreadsheets/d/1S9eM0BZyv6_OZMTXex_HrHkgpcUVSPrXzHNaW_RIPx4/edit#gid=988619344 or copy-paste the drive link in your browser.
• Open the excel sheet number 2 - MLSS Bacteriuria of the google drive link.
• Do not alter the other sheets in the google drive link which is only for reference.

9 What are the steps to put input data of patient – data 2 ?
Enter the patient name and age in the appropriate box.

10 What are the steps to put input data of patient as obligatory requirement from Simple Urine Test (SUT) results– data 3 ?

• Enter the results of the Simple Urine Test (SUT) conforming to the measurements prescribed in the 'Machine Learning Screening Software (MLSS).

• Urine pH, specific gravity, and pus cells are the primary obligatory biomarkers to be filled as numerals.

• Albumin, cast, and nitrite are secondary obligatory parameters to be filled using dropbox choosing presence or absence.

- Screeneshot of input data shown below

Machine Learning Screening Software' - MLSS - Laboratory Protocol
Predicting Bacteriuria in Pregnancy from results of Simple Urine Test (SUT)

MLSS (Bacteriuria)

MLSS predicts pregnant women who require Conventional Urine Culture Test based on the results of Simple Urine Test with an prediction accuracy of 96%.

(enter patient details and Urine Biometric test results in Blue & Amber Cells out of SUT)

Name	Sample2
Age *	22 Yrs

Urine Test report :

Biometric	Value	UOM
pH *	8	Hydrogen concentration
SPECIFIC GRAVITY *	1.01	g/cm3
PUS CELLS *	2	HPF
RBC	0	million/mm3
EPITHELIAL CELLS	0	HPF

* *Mandatory fields*

Discrete Parameter Test report			
ALBUMIN *	**Absent**	BILE PIGMENTS	Negati
CASTS *	**Absent**	BILE SALTS	Negati
COLOUR	Colourless	UROBILINOGEN	Negati
SUGAR	Nil	**NITRITE** *	Negati
CRYSTALS	Negative	YEASTS	Negati
ACETONE	Nil		

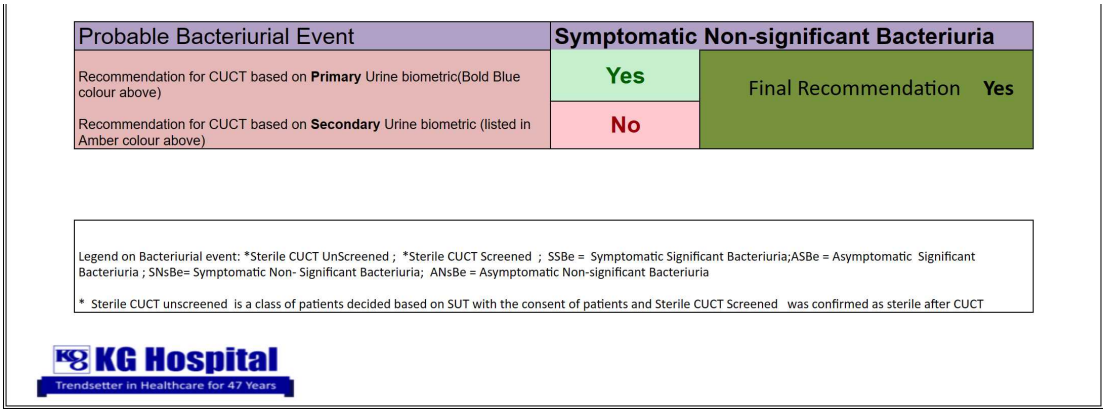
11 What are the steps to put input data of the patient as an optional requirement from Simple Urine Test (SUT) results– data 4 ?

The remaining parameters -epithelial cells, Red Blood Cells(RBC), color, sugar, acetone, crystal, bilirubin, bile salts, urobilinogen, and yeast are optional only for further clinical reference.

12 How are the results of Bacteriuria and the recommendation for Conventional Urine Culture Test (CUCT) displayed?

After entering all the input, the results will be displayed as the predicted type of bacteriurial event with or without the recommendation for Conventional Urine Culture Test (CUCT).

Display of result is shown as screenshot below,



Probable Bacteriurial Event	Symptomatic Non-significant Bacteriuria	
Recommendation for CUCT based on **Primary** Urine biometric(Bold Blue colour above)	Yes	Final Recommendation **Yes**
Recommendation for CUCT based on **Secondary** Urine biometric (listed in Amber colour above)	No	

Legend on Bacteriurial event: *Sterile CUCT UnScreened ; *Sterile CUCT Screened ; SSBe = Symptomatic Significant Bacteriuria;ASBe = Asymptomatic Significant Bacteriuria ; SNsBe= Symptomatic Non- Significant Bacteriuria; ANsBe = Asymptomatic Non-significant Bacteriuria

* Sterile CUCT unscreened is a class of patients decided based on SUT with the consent of patients and Sterile CUCT Screened was confirmed as sterile after CUCT

KG Hospital
Trendsetter in Healthcare for 47 Years

13 How was the final recommendation on Conventional Urine Culture Test (CUCT) given ?

- The final recommendation on the need for the Conventional Urine Culture Test (CUCT) will be displayed based on the recommendation by the primary and secondary biomarkers.
- If the recommendation by primary and or secondary biomarkers is " yes" proceed to Conventional Urine Culture Test (CUCT).
- Only if both primary and or secondary biomarkers recommend "NO" then no need to proceed Conventional Urine Culture Test (CUCT) but continue monitoring.

14 What is the interpretation of the results on CUCT ?

The output interpretation and subsequent course of action will be done by the Obstetrician.

15 Can the software update the history of patient records ?

This is a stand-alone protocol that needs to be documented in the respective medical/electronic records to continue the monitoring by the antenatal clinic.