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CHC CORRELATION AGAIN, - THIS TIME NON GYNAEC CYTOLOGY EXCLUSIVELY!!

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Abstract

Introduction: Fine needle aspiration cytology (FNAC) is a popular preoperative tool to plan treatment preoperatively. Therefore, validation of its reliability and usefulness is critical. Cyto-histological correlation (CHC) is a recommended quality indicator (QI) for cytopathology reporting. CHC is underutilised, though it identifies individual reporting deficit.

Aim: To evaluatereliability of non-gynaecological FNAC, using one-year data, from a rural tertiary care teaching hospital and CHC as QI.

Objective: To use the one-year retrospective CHC exercise, as a clinical audit to evaluate the usefulness of institutional cytology reporting.

Materials and methods: Retrieval of non-gynaecological FNAC and surgical pathology data for the same one-year period to find matching CHC pairs.

Results: A total of 181 non-gynaecological FNACs were done in the given time period. These were from 'Lymph node enlargements' (57), 'Breast' (39), 'Thyroid' (24) and 'Salivary glands' (12). The rest "Others" (23) were mostly soft tissue. 26 Aspirates were 'inadequate for opinion' and excluded during analysis.

FNACs were grouped into:

1. Inflammatory, including granulomatous lesions.
2. Neoplastic-benign/malignant.
3. Inadequate for opinion.

Histological correlation was possible for 45 cases (29%) (45/155). Concurrence rate for CHC was 62% (28/45) with 38% (17/45) non-concurrence. The nonconcurrence was 11% (17/155) of the total FNAC workload. These were: 29% (5/17)- 'change in categoric interpretation', 35% (6/17)- 'change within the same category', 6% (1/17) due to lack of clinical information and 29% (5/17)due to preanalytical causes of error.All non-concurrences were congruent with known limitations of FNAC leading to sampling errors and hence posed methodological queries.

Conclusions:

1. The inherent limitations of the FNAC procedure may lead to non-concurrences in CHC.
2. When hierarchical reporting is the standard protocol in an institute, this incurs a

blinding artefact to the deficits of individual reporting.

3. CHC exercise done at regular time intervals can serve as an internal clinical audit.

Keywords: Cytohistological correlation, non-gynaecological cytology, FNAC, QA in cytology laboratory

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Background: "Across the nation, laboratory professionals save lives every day by diagnosing patients"[1].

Any error in pathology laboratories is directly related to patient safety [1-4].Also, it has been empirically proven that, patients in rural areas often experience barriers to receive quality healthcare including laboratory services[5-7].This divide is particularly pronounced in case of tasks labelled "highly skilled" such as cytopathology reporting[8,9].It is therefore important to validate the reliability and usefulness of cytology reporting in every rural institutional set up [10-12], like the institute where this study was conducted.

Introduction: "In God we trust. All others please bring data" [11].

Fine needle aspiration cytology (FNAC) is a popular preoperative tool to plan treatment by differentiating between benign and malignant masses, being a minimally invasive, OPD procedure with aquick TAT[13,16].

USFDA rates cytology as high complexity reporting [8,17,18]. The accuracy and reliability of diagnosisis of utmost importance as cytological diagnosis is considered definitive for treatment planning in increasing number of cases [19,20] and depends on the knowledge, training and skill of the reporting cytopathologist[16]. Like most morphological diagnoses, cytological interpretations too are subjective and individualistic [21,22] and also requires clinical and imaging inputs[22].

"You can't fix what you don't measure"[11].The CLIA '88 Act, formulated to ensure reliable cytology reporting and thereby patient safety, specifies quality initiatives [23,24]-to remedy systemic lacunae and to ensure reporting competency of personnel[2,25-27].

'Documenting is the only way to prove doing good work'[28].Cytohistological correlation (CHC) is a quality assurance method for cytopathology recommended by College of American Pathologists (CAP) [19,28,29]. The key purpose of the CHC exercise is to identify consistent long-term deficit, in reporting, at the level of each individual screener/reporting person-so that substandard reporting does not affect patient outcomes[19,30].

At present however CHC remains a very underutilized quality assurance (QA) process for cytopathology reporting[28,29,31-33].As current flexible guidelines for CHC conduct, (allowing adaptability to different cytopathology practices) translates into variability of data generated, - having limited scope for wider comparison and applicabilityacross institutes [18,19,21,32].

We conducted a cytopathology department internal audit though a retrospective CHC exercise, using one-year data. A significant difficulty in our CHC exercise was the lack of availability of protocols specifically designed to conduct non-gynaecological cytology CHC. Thus far CHC rules used for gynaecological cytology have been applied to non-gynaecological cytology as well [10-12,32,34,35]. This does not create a good fit. Partly the

issue was also not having a clearly defined correlation of equivalence between corresponding cytopathology diagnoses and surgical pathology diagnoses.

We share here our experience of this exercise, in the sincere hope, that it helps take forward the formulation of standardized guidelines for conducting of non-gynaecological CHC

Materials and Methods

Definitions:

1. **Quality indicator:** Agency for Healthcare Research and Quality (AHRQ)'s definition- 'A quality indicator is a tool that enables the user to quantify the quality of a selected aspect of care by comparing it with a criterion. A quality indicator may be defined as an objective measure that evaluates critical health care domains as defined by the IOM (patient safety, effectiveness, equity, patient-centeredness, timelinessand efficiency), is based on evidence associated with those domainsand can be implemented in a consistent and comparable manner across settings and over time' [26].
2. **Clinical Audit (CA):** Continuous improvement programmes rooted in evidence-based medicine (EBM) wherein efficacy and performance of laboratories (including reporting) are measured against established criteria- known as Quality indicators. CA activity- Ensures quality reports and helps to identify opportunities to improve and initiate further work on lacunae[26].
3. **FNAC:** To obtain cytological material(from a lesion of interest)-by applying negative pressurewith a fine needle (22 to 24gauge)[13](1). We usually use 23-gauge needle with a 5 ml. syringe, except for thyroid cysts for which we use 22 G needle with a 10cc syringe, to attempt complete aspiration. Aspirations were done by pathologists in the pathology outpatient department (OPD), except for non-ambulatory patients. Most FNACs were from swellings on the body, very few were guided FNACs of deep lesions. All "inadequate for opinion" aspirates were by default repeated by the reporting cytopathologist, under imaging guidance, to ensure adequate yield. When a patient refused a repeat aspirate, we looked out for the CHC prospectively.
4. **CHC definition:** Per(CLIA) 1988 Act, CHC is defined as, "Comparison of preoperative cytology results with post-operative histopathology, along with clinical information,(when available) to determine whether they are concordant or discordant and then determination of the causes of any discrepancies" [19, 27].The basic premise in CHC interpretation is that site for the cytology sample and histopathology sample remains the same and the histopathology sample follows the cytology sample within a fixed duration of time (3-6 months)[19, 36].

Methods:

1. **Study design:** Retrospective Observational study.
2. **Study settings:** The present study was conducted at a rural tertiary care teaching hospital
3. **Method for collection of CHC data:**

- Data for FNAC (non-gynaecological cytology) and Surgical pathology specimens for

the samecalendar year were retrieved, to find matched CHC pairs.

- **Inclusion criteria:**Non-gynaecological FNAC samples for which corresponding surgical pathology samples were available.
- **Exclusion criteria:** Body cavity *fluid* aspirations.

4. **Method used for CHC:**There are three ways in which CHC may be conducted[Footnote 1] per the CAP Gynaecological cytology consensus working group [19, 30].We used "only paper-based review of both diagnoses" in a CHC pair, for our study. Once the pairs were found, relevant information was retrieved per essential minimum variables required for CHC analysis[Footnote2] per Raab *et al*. [27, 37]and then digitized followed by descriptive analysis (Table 1 & Table 2). This data excluded person specific details for patients and reportingpathologists.
5. **Method for analysis of CHC data:**

i)Defining of a discrepant CHC pair and assigning the type of discrepancy for each discrepant pair, was done as given in Raab & Nakhleh *et al*.[38],in table 1, page 460 [Footnote 3];with complete discordance being considered at least 2 step difference between the initial (FNAC) and revised (surgical pathology) diagnosis, (per table quoted above).

ii) Root cause analysis (RCA) of CHC discrepancies:As CHC is an error reduction exercise, discordant CHC pairs are investigated for the root cause of errors causing discordance (nonconcurrence).

Errors in CHC have been labelled as

a) Sampling and Interpretative by Clary[35] and Nodit [21].
b) Active and latent by Raab and & Grzybicki [27].
c) The "no blame model" proposed by Raab & Grzybicki [37].This model seeks to address the risk-taking capacity of each individual pathologist, defined as, -the willingness to commit to a definitive diagnosis in the face of less than an ideal smear.

Irrespective of the label, root causes of errors may be classified into interpretation (analytic) errors or specimen procurement (pre-analytic causes). The latter are sampling errors or errors due to systemic lacunae,-in specimen procurement, processing or handovers[11]-further classified into 3 domains: technical, organizational, and human, per Eindhoven model[Footnote 4], as given in Raab, Grzybicki, table 4, page 328[27]. However, we chose to not further classify these as "Active" (errors or failures that result from human behaviour) or "Latent" (organizational/technical) errors [27], in orderto maintain the focus on a solutions-oriented approach.

6. **Assessment of patient harm status as a result of discrepancies**

Nonconcurrences amount to medical errors [27].The degree of gravity of all 'possible' discordances, was assessed in terms of patient harm caused. For assessing error induced patient harm status, we used the definition[Footnote 5] given in Raab & Grzybicki *et al*. [27] in

Footnote [1] For details of CHC methods-Please check Note 1 in Supporting material provided.
[2] For details, check note 2 in Supporting material.
[3]For details, check note 3 in Supporting material.
[4]For details, check note 4 in Supporting material.
[5]For details, check note 5 in Supporting material.

table 5,page 302.

Results:

The Study results data were studied using descriptive analysis and are tabulated as follows:

- **Table 1:** Basic overview of FNAC samples and CHC pairs.
  A total of 181 non-gynaecologic FNACs were done in the given time period from 170 patients. 11 FNACs were repeat FNACs. For the analysis of the aspirates as well as the CHC pairs, we considered as the denominator, the 155 FNACs that were adequate for a diagnosis and the related 45 CHC pairs.
- **Table 2:** Descriptive analysis of CHC pairs data.
  Predominantly, (84%) of CHC pairs from all organs showed benign lesions, although this could be a reflection of the bias inherent in the FNAC data.
- **Table 3:** CHC pairs-Possible Nonconcurrences analysis and suggested remedial actions, with patient harm status.
  For 17 out of the 45 CHC pairs (38%) we were unable to neatly pigeon hole these CHCdiscrepancies into non-concurrences or otherwise and hence we termed these as "possible non-concurrences".
  All were congruent with known limitations FNAC and hence posed methodological queries. The nonconcurrences amounted to 11% (17/155) of the total FNAC workload.
- **Table 4:** Organ wise descriptive analysis of CHC data,
  i) Percentage of CHC pairs with two different denominators:
    a) The total number of FNAC samples (The total cytology workload).
    b) The total number of CHC pairs.
  ii) Organ wise distribution of '*number of CHC pairs for discussion'* with both the denominators above.
  Histological correlation was possible for 45 cases (25%) (45/181).While there is no proscriptive value for minimum number of CHC cases, this value was compliant with the CLIA'88 guidelines mandate to retrospectively review/rescreen at least ten (10) percent of preoperative cytology cases with postoperative histopathology correlation[19, 29].
  Although the maximum number of aspirates were from Lymph nodes (LN), (57 out of 181) (31%), -this was not reflected in the CHC pairs. Possibly, because most LN enlargements tend to regress with antibiotic therapy. Breast and thyroid swellings were apparently most operated upon, likely because, for the patients, swellings in these sites caused cosmetic worries and anxiety due to the possibility of a malignant tumour.
- **Table 5:** Discrepant CHC pairs with 'Root cause analysis' and systemic lacunae with suggested corrective actions.
- **Table 6:** Comparison of organ-wise discrepancy percentages with other studies.
- **Table 7:** Description of the Nonconcurrences (discrepancies) with explanation.
  CHC for this study showed a concurrence rate of 62% with 38% CHC pairs showing discrepancy between the cytological and histopathological diagnoses. Of these, 29% (5/17), were 'change in categoric interpretation' and 35% (6/17)- 'change

within the same category'.6% (1/17) were non-concurrent due to lack of or miscommunication of clinical information.Yet another 29% (5/17) were in the category of 'Other issues', such as preanalytical causes of error or inadequate sampling by clinicians.

- **Table 8:** Comparison of salient observations regarding the CHC process from our study with other authors.

CHC-Discussion

I)Methodology

CHC Study results depend on the methodused for collection as well analysis [38, 39], hence a brief explanation of our choice of method used for CHC data collection. There were several circumstances that contributed to choosing only paper-based comparison of diagnoses,

1. In the absence of a computerized laboratory information system, the manual effort required just to collect the CHC pairs data was expected to be significant [19].
2. Review process of actual slides by another pathologist, was expected to have limited pertinence due to,
   a) Invariable differences of individual opinion[21, 39].
   b) Because pathologists are known to contradict their own prior opinions at times[40].
3. Our institution's system of hierarchical reporting for FNAC cases, ensured that, the final sign out was 'the diagnosis of concurrence'[41],after a review by at least 2-3independent qualified pathologist(s). This process also compensated for the risk-taking capacity of each individual reporting pathologist. Also, hierarchy does not preclude open professional opinion sharing in our institute[42]. So, employing another "independent" pathologist for review of slides, seemed redundant.
4. Plus, for all FNAC cases received in the cytology department of the institute, there is a prospective CHC evaluation, upon receiving the surgical pathology specimen in the pathology department. This prospective CHC exercise is done with review of actual slides. Thus, repeating of glass slide review also seemed pointless.
5. Most importantly, we wanted to get started with the process of long-term data analysis for quality of cytological reporting, as retrospective CHC data analysis is the only method to achieve error reduction and for determining allowable margins of error for cytological reporting[19, 32].Waiting for all the best possible variables, seemed only to be a non-starter.

We share our experience of this exercise, in the sincere hope, that it helps take forward the formulation of standardized guidelines for conducting of non-gynaecological CHC.

Lack of standardization of the CHC process poses limitations upon comparison of inter-institutional data[26, 35, 38].While, the conundrum is that, quality related error reduction exercises stress upon a long-term follow-up of data and sharing of data as an important part of moving towards standardization of allowablemargins of error and thereby keeping up the cycle of continuous quality improvement[27].

II) General observations as regards the CHC process during our study.

1. Defining a standardised protocol for Non gynaec CHC, comparable to the Gynaec CHC protocol.

To be able to define/generate meaningful allowable margins of error,

a) There needs to be long term follow up of an institution's own data, in a consistent format.

b) Availability of error rates from other (comparable) institute(s) for comparison.

As a result of our study, we felt therefore, that there is a need to deal with the factors that lead to variability in output data [32] such as,

i) The random nature of recording/conduct [11, 26, 35, 39] of a CHC exercise, especially non-gynaec CHC.

ii) The random nature of CHC pairs that may come up for correlation-with practice specific predominance of cases, and differing approaches to treatment [21].

iii) The differing reasons and hence approaches for conducting institutional CHC exercises [38].

iv) Possible ways to circumvent the difficulty in tracing slides for surgical specimens because care is *actually* fragmented[19, 30].

As opposed to this, the process of standardisation achieved by Gynaecological cytology CHC[19], is such that,

a) Congruent corresponding terminologies have been established between the equivalent cytopathological and surgical pathological diagnoses-to determine the type and stage of cervical pathology [32].

b) The clinical treatment is aligned to the disease stage thus determined.

None of this is as yet applicable in the case of non-gynaecological cytology, creatingmethodological hurdles, such as we experienced. We suggest, therefore stipulating for non gynaec CHC conduct:

i) a bare minimum precise number of lesions, -

ii) from specific sites

iii) for specific diagnoses

iv) for specific kind of discordance,

v) with mandatory annual CHC as a clinical audit

vi) define specific time interval for batchwise analysis, in the interim period before the one year is up.

-as has been done for Gynaecological cytology [19]]. It appears that implementing this protocol would make the output of the CHC exercise muchmore useful for inter-institutional sharing [32].

2. **Need for creating a system for recording individual pathologist's opinion in each case, in the setting of institutional hierarchical reporting**.

The elegant feature of CHC is providing feedback on the reporting proficiency of each individual reporting pathologist. Therefore, 'Proficiency testing' for screeners, which has not been shown to be very useful [26, 44] and is basically too low level for most adept cytopathologists/technologists [26, 29]-may be done to complement the CHC exercise, rather than the other way round, as is done presently. However, when hierarchical reporting is the standard protocol in an institute, this incurs a blinding

artefact to the deficits of individual reporting personnel. Therefore, there appears to be a need to set up a system whereby each individual pathologist's record may be maintained for evaluation and further suitable action, if required.

3. **Routine usage of image guidance for all FNACs.**
   As has already been said in literature [16], a combination of modalities, that is routinely using imaging guided FNACs (instead of the blind procedures used currently)is needed. This will reduce sampling errorsthat is aspirates that result in 'Inadequate for opinion' (IFO) diagnosis. (Figures 1,2,3,4).

III)Analysis of results

Our study, showed that, simply noncongruent diagnoses in a CHC pair, may be a reflection of accepted limitations of sampling and/or interpretation of FNAC procedure.Hence clarity regarding when to actually consider a CHC pair diagnoses as nonconcurrent-is much needed, if CHC is to be a useful quality indicator. (Table 3,4 and Table 7)

Also, it must be recognised that a) as most cytology samples are *not* followed by biopsy samples, the CHC pairs data is a very biased sample, so the error rate needs to be levelled with the total work load. This is imperative since the CHC process is used to document individual error record, mostly the cytopathologist's[27, 33].

IV) Organ system/site specific CHC correlation issues: (Table 3)

i) LN: For the five LN cases that are up for discussion, common points summarized are just two, possibly three. Two of the five cases belonged to an axillary dissection in cases of modified radical mastectomy. The point being, whether this, -the inability of a blind FNAC procedure to detect malignant deposits when only occasional lymph node in the entire lymph node group is involved, -amount to a nonconcurrence? (Figure 2). Adequate communication between clinicians and pathologists is a must to avoid these situations [11].

ii) Breast: Breast cases that came up for discussion were again five, bringing forth several different issues.

A pertinent finding was that there is no equivalent surgical pathology diagnosis for 'suspicious or atypical' cytology.

The other important point was, when the histopathology sample- the gold standard[33, 39] in the CHC process, fails to deliver due to inadequate biopsy, how then to interpret the CHC correlation?Besides, tissue correlation may not be the best gold standard for evaluating CHC [27, 28]. As,

a) Histopathological diagnosis is liable to change on review or upon application of corrective measures, -such as deep cut or reorientation of block [19, 32, 33].
b) Has its own share of wrong diagnoses [19, 27, 28, 30].
c) Biopsy samples have sampling errors, from the time lag-between FNAC and biopsy, the decreasing size of the lesion, and also due to being interpreted in light of the previous biopsy/FNAC.

This is an important consideration when evaluating CHC non-concurrences, asthen, it is mostly the cytology diagnosis that is looked up for"errors of accuracy and errors of

precision" [27],with the pathologist's culpability being the issue[33].

Another point for clarification was, cytology is mainly used to differentiate between a benign and malignant lesion, so when a diagnosis changes within the same category, or from inadequate on cytology to a benign HPE diagnosis, how might this be interpreted in the CHC process, specifically-as regards the pathologist's error record? (Figure 3).

This is an important consideration when evaluating CHC non-concurrences, asthen, it is mostly the cytology diagnosis that is looked up for"errors of accuracy and errors of precision" [27],with the pathologist's culpability being the issue[33].

iii)Thyroid, Salivary glands and "Other sites":

Some entities such as follicular adenoma (thyroid), need confirmation of intactness of the adenoma capsule on HPE and therefore as such cannot be diagnosed on FNA. So then whether TBSRTC-II might be considered a concurrent diagnosis on cytology for this lesion? -or not?

Similarly, TBSRTC-I- effectively synonymous with inadequate aspirate/cystic lesion of thyroid-if diagnosed as colloid haemorrhagic cyst on histopathology (TBSRTC-II on cytology)-is this to be considered a non-concurrence?

Also, for sampling inadequacies, if the root cause analysis showed the lesion to be inaccessible, as in a thyroid cyst, with or without USG guidance, (because aspirations in the neck region are tricky) -then how can sampling inadequacies due to reasons beyond the control of the aspiration performing personnel, be considered a non-concurrence? (Figure 4)

V)Analysis of data results with a comparison of error percentage with other studies:

This is not possible, for various reasons as follows:

a) As there are almost no comparable published studies available for interlaboratory comparisons of diagnostic errors[28]and also the lack of standardized methodology to conduct CHC exercise makes comparison of any statistic difficult[39, 45].
b) Any statistic obtained by a particular cytology practice-could simply be the reflection of the randomness of the CHC pairs that got retrieved as a part of the exercise, a known glitch in the process[21, 33].
c) The percentages of CHC pairs that get shortlisted for discussion for each organ/site is also random and partly a reflection of the total CHC pairs retrieved/are practice specific.
d) Also, this whole data is biased because most cytological smears are normal and therefore do not get followed by tissue samples that may be correlated[19, 28].

Therefore, this over all biasedness of data, makes it impossible to compare CHC analysis results between different practices. (Table 6 has been compiled to illustrate this point).

VI)Methodological difficulties encountered in CHC process of the study undertaken (Table 8):

The current prevalent system of considering a reporting error or a non-concordance as the personal culpability of the reporting cytopathologist(s)/individual, rather than considering it a systematic error, [11, 19, 27, 37, 39, 46], is a hinderance in sharing data and using

CHC as a QI.This is an outlook that needs updating. More importantly, it is gives the necessary recognition to the fact that in case of humans, errors are inevitable, although never intentional[27].Therefore, this kind of blame game is unfair and also very avoidable.

Perhaps health care field too ought to adopt relevant safety related root cause analysis practices prevalent in business or industry, such as 'asking why?at least 5 times', when investigating an incident[11, 47].

VII) Root cause analysis (RCA)

As CHC is an error reduction exercise, RCA is a key part of error reduction by means of CHC. Discordant CHC pairs are investigated for errors causing discordance (nonconcurrence) between the cytological and histological diagnosis. Then root-cause analysis is done to investigate the lacunae in existential systems leading to these errors.

In order to be able to work on a root cause analysis, it is first necessary to label and classify the errors causing discordance. As explained in the Results section, the non-concurrences in this study only brought up methodological issues, so we labelled these as "Unclassifiable" per the Eindhoven model (EHM) per Raab Grzybicki[27]. We then looked to separate these issues into root cause domains of human, organizational and technical per the EHM.

The pathology laboratory is a complex system of functioning with many handovers and interfaces, with a large scope of pre-analytic errors[11, 42, 45].(Figure 5). As Pathologists we work to minimize uncertainty in a very limited field, despite which, all we want is to do our best for the patients. Refer to (Figure 6) below-adapted for our study,-from the NHS Devonshire Quality and Performance booklet, Version 2[48]or to"The total testing process (TTP)" [figure 2-from Raab and Grzybicki [11]].

So, we wanted to keep our root cause analysis grounded in system-based lacunae with a solutions-oriented focus. Explained in (Table 5).

Conclusions

1. The inherent limitations of the FNAC procedure may lead to non-concurrences, in CHC exercise. For non gynaec cytology CHC needs formulation of specific guidelines.
2. When hierarchical reporting, is the standard protocol in an institute, this incurs a blinding artefact to the deficits of individual reporting personnel.
3. CHC exercise done at regular time intervals can serve as an internal clinical audit.

Limitations of the study

1. Sample size is low for both cytology aspirates as well as CHC pairs.
2. Only paper-based review of both cytological and surgical pathological diagnoses in a CHC pair, was done.
3. Single institution study.

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TABLES

1) **Table 1:** Basic overview of FNAC samples and CHC pairs

Table I

Specimen type	Breast			Thyroid			Lymph node			Salivary glands			Others			Inadequate for opinion			Total	
	FNAC # (Number)	% of Organ specific FNACs	% of Total FNACs	FNAC # (Number)	% of Organ specific FNACs	% of Total FNACs	FNAC # (Number)	% of Organ specific FNACs	% of Total FNACs	FNAC # (Number)	% of Organ specific FNACs	% of Total FNACs	FNAC # (Number)	% of Organ specific FNACs	% of Total FNACs	FNAC # (Number)	% of Total FNACs	Total FNACs # (Number)	% of Total FNACs
																			of the 155 reported FNACs
Total	39		0.25	24		16%	57		36%	12		7%	23		15%	26	14%	181	100
Benign	35	90%	0.22	23	96%	14%	54	95%	34%	11	92%	7%	21	91%	14%			144	93%
Malignant	4	10%	0.03	1	4%	2%	3	5%	2%	1	8%	<1%	2	9%	1%			11	7%
Total reported FNACs																		155	86% of the total 181 FNACs
CytoHisto correlation	16	41%	s	9	37%	6%	10	18%	6%	3	25	2%	7	30%	5%	1		45%	29%

	# (Number)	% of organ specific CHC pairs	% of Total CHC pairs	# (Number)	% of organ specific CHC pairs	% of Total CHC pairs	# (Number)	% of organ specific CHC pairs	% of Total CHC pairs	# (Number)	% of organ specific CHC pairs	% of Total CHC pairs	# (Number)	% of organ specific CHC pairs	% of Total CHC pairs	# (Number)	% of organ specific CHC pairs	# (Number)& % of Total CHC pairs	% of Total FNACs
Benign	13	81%	8%	8	89%	6%	8	80%	5%	2	67%	1%	7	100%	5%	1		38 (84%)	25%
Malignant	3	19%	2%	1	11%	<1%	2	20%	1%	1	33%	1%	0	0	0	0		7 (16%)	5%

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Table 2: Basic overview of the CHC pairs data

CHC pairs	Benign	Malignant	Total
Breast	13	3	16
LN	8	2	10
Thyroid	8	1	9
Salivary gland	2	1	3
Other	7	0	7
TOTAL	38	7	45
Percent	84%	16%	

Table 3:CHC pairs-Organ wise tabulation of a) nature of discrepancy and b) patient harm status

Table 3: CHC pairs organ wise tabulation of nature of discrepancy and patient harm status

Sr. No.	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Discrepancy type	Nature of error and Explanation	Comment	(Whether) Patient harm done and explanation
1	LN	Reactive Lymphadenitis	Ductal Carcinoma Breast (pT2N2Mx; MBRE grade2, 4/27 LNs involved.)	Whther this is to be considered a Non-concurrence ?	Discrepancy status-Moot-To be discussed further as a CHC methodological query.	Pre-Analytical error. (Sampling error.)	Known and accepted limitation of FNAC procedure.	Patient harm done: None.	The treatment remained the same irrespective of the FNAC report. Axillary LN dissection was done as always-with the modified radical mastectomy.(MRM)
2	LN	Microscopic findings suggestive of (?) Quiescent lymph node. There were no changes suggestive of lymphadenitis in the aspirated Lymph node	Granulomatous lymphadenitis with morphology of granulomas suggestive of Tuberculous granulomas.	Non-concurrence present between cytological and HPE diagnosis.	Change in the patient related information	●Pre-analytical error [requisition form lacked significant required information) : FNAC done on Axillary lymph nodes and HPE on Abdominal (peritoneal) nodules.]	This is a typical case of lack of communication between clinicians and pathologists. The lymph node that was aspirated was axillary. When the HPE showed frank TB granulomas, we went back to the patient indoor papers and found that those submitted for HPE were peritoneal LNs. However it brings to mind, the question -whether axillary LNs would remain completely quiescent in a case of tuberculous peritonitis? How do we classify this wrt to concurrence or otherwise?- although this case does not strictly fit into the CHC definition of cytology (same site cytology and histopathology), how to classify a situation like this , with respect to, a system like Lymph nodes in case of diseases like TB which mostly cause generalized lymphadenopathy??	Known and accepted limitation of FNAC procedure. Non availability of clinical information severly hampers interpretation of the pathology samples.	Patient harm done: none.	Patient came with abdominal symptoms and underwent exploratory laparotomy since everything else came up negative except few peritoneal nodules that the imaging could not assign a cause to.
3	LN	Lymph node aspirate smears NEGATIVE for malignant cells	1/8 LNs involved. (Rt MRM Axillary dissection. 8 LNs identified, largest 2.5 cm, with cystic change)	Is this to be considered a Non-concurrence ?	Discrepancy status-Moot-To be discussed further as a CHC methodological query.	Pre-analytical (Sampling) error.	Known and accepted limitation of FNAC procedure.	Patient harm done: None.	Since the treatment remained the same. Axillary LN dissection was done with the MRM.
4	LN	Granulomatous lymphadenitis	Reactive lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Pre-analytical (Sampling) error.	Known and accepted limitation of FNAC procedure.	Patient harm done: None.	1.Since the treatment for TB was initiated basis cytology when FNAC aspirate smear was positive for AFB. (Excised LN material was sent for CBNAAT. For confirmation) Thus for the patient treatment remains the same. 2. Operative procedure for LN biopsy was not done unnecessarily since legally it is mandatory to perform LN biopsy for documentation of diagnosis.
5	LN	Reactive Lymphadenitis	Caseating tuberculous lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Pre-analytical (Sampling) error	Known and accepted limitation of FNAC procedure.	Patient harm done : None.	As both cytological and histological diagnoses remained benign and were varieties of chronic lymphadenitis. We then started doing AFB staining for detection of likely TB bacilli (morphological diagnosis only) on all suspected cases of TB Lymphadenitis.

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Table 3: CHC pairs-Organ wise tabulation of a) nature of discrepancy and b) patient harm status-Contd.2

Table 3: CHC pairs organ wise tabulation of nature of discrepancy and patient harm status

Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Discrepancy type	Nature of error and Explanation	Comment	(Whether) Patient harm done and explanation
6	Breast	Benign proliferative breast lesion with focal atypia in the form of three dimensional cellular clusters, overlapping of nuclei and focal areas of coarse chromatin. Nuclear membranes remained regular for all cells.	Fibrocystic disease of breast with focal atypical proliferation of ductal cells and sclerosing adenosis focally.	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Systematic error. Lack of uniform terminology across cytopathology and surgical pathology for breast lesions.	Known and accepted limitation of FNAC procedure.	Patient harm done-None. Since the treatment remains the same, and the nature of lesion remains correctly diagnosed as benign on both modalities.
7	Breast	No opinion possible	HPE picture consistent with fat necrosis of breast.	Whther this is to be considered a Non-concurrence ?	Discrepancy status-Moot-To be discussed further as a CHC methodological query.	Pre-analytical (Sampling error?)	Since the lipoid material aspirated was likely dissolved in the organic solvents during the staining process. Thus acellular smears remained upon staining for cytological evaluation.	Known and accepted limitation of FNAC procedure. Whether retaining atleast one Air dried smear might avoid this situation?	Patient harm done-None. Since the treatment remained the same. Also patient was anxious due to the space occupying nature of this lesion and wanted to have it removed .Surgical treatment is the ideal treatment for fat necrosis breast that does not resolve over time.
8	Breast	Benign breast lesion, favour fibroadenoma. Occasional cluster of atypical breast ductular epithelial cells seen.	Benign phyllodes tumour	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Systematic error. Lack of uniform terminology across cytopathology and surgical pathology for breast lesions. Therefore,Discrepancy status- Moot-To be discussed further as a CHC methodological query.	The presentation of a benign proliferative breast lesion on cytology prompts favoring of the commonest lesion- Fibroadenoma (FA). Also FA is considered the closest differential for Phyllodes tumour breast and spindle cells diagnostic of the Phyllodes tumour may be rare or absent in the FN aspirate.	Known and accepted limitation of FNAC procedure.	Patient harm done-None. Since the treatment remains the same, and the benign nature of lesion is correctly diagnosed.
9	Breast	Benign proliferative lesion.	Trucut biopsy inadequate for opinion	Non concurrence status: Not known.	Discrepancy status-Moot-To be discussed further as a CHC methodological query.	When the gold standard for CH correlation - the histopath diagnosis is not up to standard, then how to proceed for CH correlation?	Error status: Not known. possibly because in case of breast FNACs labeling an aspirate as proliferative lesion is a way to sit on the fence for the cytopathologist, since very often imaging findings are not available and cytological atypia does not match with the totally benign clinical findings of the lump. At the same time, on microscopic appearance, the lesion falls short of suspicious or atypical but does not look completely harmless either .	Whether speciality consultation might help in honing of the FNAC consult in dubious/suspicious cases	Patient harm status: Not known. Patient lost to follow up. Care is fragmented and sometimes ideal conditions for CH correlation are not possible.
10	Breast	Proliferative breast lesion.	Histologic picture consistent with breast abscess (Multiple fragmented breast tissue bits received)	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Pre-Analytical (Sampling) error and possibly also other interfering factors in the interval between FNAC and surgical process leading to error.	Sampling error of aspirating the surrounding reaction to the abscesses on FNAC , which was interpreted as proliferative lesion. Or , less likely possibility of infection being introduced during FNAC thus turning fibrocystic disease lesions into abscesses,seen on histopathology.	Known and accepted limitation of FNAC procedure.	Patient harm: None. Since the treatment remains the same, and the nature of lesion remains correctly diagnosed as benign on both modalities.

Table 3: CHC pairs-Organ wise tabulation of a) nature of discrepancy and b) patient harm status-Contd.3

Table 3: CHC pairs organ wise tabulation of nature of discrepancy and patient harm status

Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Discrepancy type	Nature of error and Explanation	Comment	(Whether) Patient harm done and explanation	
11	Thyroid	TBSRTC-I. Only cyst fluid or inadequate for opinion. Note: Large cyst may harbor a malignant focus on the side.	Nodular goiter with dominant hemorrhagic cyst.	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	1.Pre-analytical (Sampling) error. Or limitation of FNAC process, in this particular situation of a dominant haemorrhagic cyst in nodular goitre. 2.Also the category TBSRC -I comprises of inadequate aspirations as well as only cyst fluid. Thus terminology across cytology and surgical pathology is non uniform causing non concurrence issues.	Haemorrhagic fluid on a large thyroid cyst aspiration will raise a flag of suspicion.	Known and accepted limitation of FNAC procedure.	Patient harm status: None.	Since treatment will remain same. Right lobe of thyroid removed. Possibly because of large cyst size, possibly because a cystic lesion could harbor a potential focus of malignancy. Also most thyroid lesions in the study population were operated for cosmetic reasons and due to anxiety over the mass seen rather than any other.
12	Thyroid	TBSRTC -II. Benign thyroid pathology. Favour: Colloid goitre with cystic change	Follicular adenoma	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	1.Pre-analytical (Sampling) error. Or limitation of FNAC process, in this particular situation of a spacr occupying lesion in nodular goitre. 2.Also the category TBSRC -II comprises of all benign thyroid lesions including follicular adenoma which is infact a benign neoplasm. Thus terminology across cytology and surgical pathology is non uniform causing non concurrence issues.	Diagnosis of a follicular adenoma in thyroid is a function of the completeness of the wall of this neoplasm. Therefore establishing this diagnosis is only possible on histopathology.	Known and accepted limitation of FNAC procedure.	Patient harm status: None.	Since treatment will remain same. Right lobe of thyroid removed. Possibly because of large size of lesion. Also, most thyroid lesions are operated for cosmetic reasons rather than any other.
13	Thyroid	Acellular smear. No opinion possible.	Multinodular goiter.	Non - concurrence of cytological and histological diagnosis.	Discrepancy status- Moot- To be discussed further as a CHC methodological query.	Pre-Analytical error. (Sampling error.)	There was no cellularity to be reported on cytology. HPE reported benign lesion.	Known and accepted limitation of FNAC procedure.	Patient harm status: None.	In this case, patient wanted the lesion to be removed for cosmetic and other reasons (anxiety).
14	Thyroid	FNAC: TBSRTC-I (Cystic fluid only)	Colloid hemorrhagic cyst	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	1.Pre-analytical (Sampling) error. Or limitation of FNAC process, in this particular situation of a dominant cyst in nodular goitre. 2.Also the category TBSRC -I comprises of inadequate aspirations as well as only cyst fluid. Thus terminology across cytology and surgical pathology is non uniform causing non concurrence issues.	Aspiration of acellular fluid on a large thyroid cyst aspiration will necessarily be reported as TBSRTC-I	Known and accepted limitation of FNAC procedure.	Patient harm status: None.	Left lobe of thyroid removed. Possibly because of large cyst size, or possibly because a cystic lesion could harbor a potential focus of malignancy.

Table 3: CHC pairs-Organ wise tabulation of a) nature of discrepancy and b) patient harm status-Contd. 4

Table 3: CHC pairs organ wise tabulation of nature of discrepancy and patient harm status										
	Sr. No.	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Discrepancy type	Nature of error and Explanation	Comment	(Whether) Patient harm done and explanation	
	15	Others	No opinion possible	Lipoma	How to classify this? Concurrence or not.Since Cytological and histological diagnoses differ.	Discrepancy status- Moot- To be discussed further as a CHC methodological query.	Pre-analytical (Processing) error.	Lipomatous tissue dissolves on fixing in organic solvents. Air dried smears stained with Romanowaski stains also dissolve this material during processing. Thus leaving acellular smears.	Known and accepted limitation of FNAC procedure.	No patient harm done,	Since treatment remained the same. Patient wanted the lesion to be removed for cosmetic and other reasons (anxiety).
	16	Others	No opinion possible. Please correlate clinically.	Neurilemmoma	How to classify this? Concurrence or not.Cytological and histological diagnoses differ.	Discrepancy status- Moot- To be discussed further as a CHC methodological query.	Pre-analytical (Sampling error).	This was a soft tissue mass , asymptomatic but aspiration attempts were very painful for the patient and did not yield any cellular content on repeated aspirations.	Sampling limitations are -Known and accepted limitation of FNAC procedure.	No patient harm done,	Since treatment remained the same. Patient wanted the lesion to be removed for cosmetic, functional and other reasons- anxiety
	17	Salivary gland	Likely chronic sialadenitis. However possibility of pleomorphic adenoma cannot be ruled out in the given smear appearance.	Reactive follicular hyperplasia of LNs within the salivary glands.	Non-concurrence present between cytological and HPE diagnosis.	Change within the same category of interpretation: An interpretation was changed from one benign interpretation to another benign interpretation.	Pre-analytical (Sampling error).	This was a very unusual situation of hyperplastic lymphoid tissue withing the parotid gland causing a salivary gland mass-are not detected as such on sonography. FNAC reporting is again dependent on sonography findings.	Sampling limitations are -Known and accepted limitation of FNAC procedure.	Patient harm done- None,	As treatment remained the same. Long standing lesion x 3 years. Painless. Slow growing. However on repeated aspirates no salivary duct cells were found to be present on the smears. Necrotic material and the elongate cells likely young fibroblasts raised the doubt of neoplasm on aspirate.

Table 4: Organ wise split of cases showing "possible" non-concurrence

Table 4						
Organ wise split for CHC pairs for discussion						
Sr. Number	Organ/Site	Number of possible non-concurrence - organ /site wise = N	'N' as Percentage of CHC pairs for discussion = (17)	'N' as Percentage of total number of CHC pairs per organ /site: % (#)	'N' as Percentage of the total CHC pairs found (45)	'N' as Percentage of total number of FN aspirates - organ/site wise workload & (% Total workload)
1	LN	5	29%	50 % (5/10)	11 % (5/45)	9 % (5/57)
2	Breast	5	29%	31% (5/16)	11% (5/45)	13 % (5/39)
3	Thyroid	4	24%	44% (4/9)	9% (4/45)	17 % (4/24)
4	Others	2	12%	29% (2/7)	4% (2/45)	9 % (2/23)
5	Salivary gland	1	6%	33% (1/3)	2% (1/45)	8 % (1/12)
Total		17			37.78% (17/45)	10.97% (17/155)

Table 5: (Possibly) Discrepant CHC pairs with CHC methodological queries and systemic lacunae/suggest ed corrective actions

Table5: Discrepant CHC pairs with CHC methodological queries and systematic lacunae /corrective actions

Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Point to be made, regarding conduct of CHC process	Domain of methodological issue	Corrective systematic action
1	LN	Reactive Lymphadenitis	Ductal Carcinoma Breast (pT2N2Mx; MBRE grade2, 4/27 LNs involved.)	Whther this is to be considered a Non-concurrence ?	Whether this is to be labeled-Non concurrence and then a cytology error?? - as there is an apparent 2 step discrepancy between the cytology and histological diagnosis . However on HPE (4/27) LNs identified contained malignant deposits and the largest LN also showed cystic change. Also this kind of nonconcurrence is a known limitation of FNAC procedure. So does this even merit being labeled as : a sampling error?	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
2	LN	Microscopic findings suggestive of (?) Quiescent lymph node. There were no changes suggestive of lymphadenitis in the aspirated Lymph node	Granulomatous lymphadenitis with morphology of granulomas suggestive of Tuberculous granulomas.	Non-concurrence present between cytological and HPE diagnosis.	Does not strictly fit into the CHC criteria of cytological and histological sample from same site. But still included to show how proactiveness on the part of pathologists may change an apparent non-concurrence.	(Organisational domain-Culture)	Communication needed between operating teams and pathologists interpreting the sample.
3	LN	Lymph node aspirate smears NEGATIVE for malignant cells	1/8 LNs involved. (Rt MRM Axillary dissection. 8 LNs identified, largest 2.5 cm, with cystic change)	Is this to be considered a Non-concurrence ?	Whether this is to be labeled-Non concurrence?? Since on HPE (1/8) LNs identified contained malignant deposits . Also this kind of nonconcurrence is a known limitation of FNAC procedure. So does this even merit being labeled as: a sampling error"??	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
4	LN	Granulomatous lymphadenitis	Reactive lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	Whether this is to be labeled-Non concurrence?? Since, in this case on cytopathology- the diagnosis was chronic granulomatous lymphadenitis. This cannot be considered analytical error due to hierarchical reporting by several faculty before sign out. However it is difficult to explain why the granulomas were not seen in the HPE. Most likely, the operating surgeon did not excise the LN subjected to FNAC but excised another axillary LN. So whether this should be considered as non-concurrence for CHC or sampling error during biopsy??	1.(Organisational domain-Protocol and culture) 2.(Human domain- coordination)	1.Communication needed between operating teams and pathologists interpreting the sample. (Organisational domain-Protocol and culture) 2.Duration between the FNAC and biopsy procedure needs to be noted and any intervening therapy too.
5	LN	Reactive Lymphadenitis	Caseating tuberculous lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	So is this to be considered as non concurrence or what? Since this is an accepted limitation of the procedure of FNAC procedure, that the focus of caseation and granulomatous change may not be accessed in the FNAC. This is especially true in case of large lymph nodal enlargement, deep cervical lymph nodes and paediatric patients.(*)	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.

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Table 5: (?) Discrepant CHC pairs with CHC methodological queries and systemic lacunae/suggested corrective actions. -Contd.2

Table5: Discrepant CHC pairs with CHC methodological queries and systematic lacunae /corrective actions

Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Point to be made, regarding conduct of CHC process	Domain of methodological issue	Corrective systematic action
1	LN	Reactive Lymphadenitis	Ductal Carcinoma Breast (pT2N2MX; MBRE grade2, 4/27 LNs involved.)	Wrther this is to be considered a Non-concurrence ?	Whether this is to be labeled-Non concurrence and then a cytology error?? - as there is an apparent 2 step discrepancy between the cytology and histological diagnosis. However on HPE (4/27) LNs identified contained malignant deposits and the largest LN also showed cystic change. Also this kind of nonconcurrence is a known limitation of FNAC procedure. So does this even merit being labeled as : a sampling error?	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
2	LN	Microscopic findings suggestive of (?) Quiescent lymph node. There were no changes suggestive of lymphadenitis in the aspirated Lymph node	Granulomatous lymphadenitis with morphology of granulomas suggestive of Tuberculous granulomas.	Non-concurrence present between cytological and HPE diagnosis.	Does not strictly fit into the CHC criteria of cytological and histological sample from same site. But still included to show how proactiveness on the part of pathologists may change an apparent non-concurrence.	(Organisational domain-Culture)	Communication needed between operating teams and pathologists interpreting the sample.
3	LN	Lymph node aspirate smears NEGATIVE for malignant cells	1/8 LNs involved. (Rt MRM Axillary dissection. 8 LNs identified, largest 2.5 cm, with cystic change)	Is this to be considered a Non-concurrence ?	Whether this is to be labeled-Non concurrence?? Since on HPE (1/8) LNs identified contained malignant deposits . Also this kind of nonconcurrence is a known limitation of FNAC procedure. So does this even merit being labeled as: a sampling error"??	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
4	LN	Granulomatous lymphadenitis	Reactive lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	Whether this is to be labeled-Non concurrence?? Since, in this case on cytopathology- the diagnosis was chronic granulomatous lymphadenitis.This cannot be considered a analytical error due to hierarchical reporting by several faculty before sign out. However it is difficult to explain why the granulomas were not seen in the HPE. Most likely, the operating surgeon did not excise the LN subjected to FNAC but excised another axillary LN. So whether this should be considered as non-concurrence for CHC or sampling error during biopsy??	1.(Organisational domain-Protocol and culture) 2.(Human domain- coordination)	1.Communication needed between operating teams and pathologists interpreting the sample. (Organisational domain-Protocol and culture) 2.Duration between the FNAC and biopsy procedure needs to be noted and any intervening therapy too.
5	LN	Reactive Lymphadenitis	Caseating tuberculous lymphadenitis	Non-concurrence present between cytological and HPE diagnosis.	So is this to be considered as non concurrence or what? Since this is an accepted limitation o f the procedure of FNAC procedure, that the focus of caseation and granulomatous change may not be accessed in the FNAC. This is especially true in case of large lymph nodal enlargement, deep cervical lymph nodes and paediatric patients.(*)	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.

Table 5: (?) Discrepant CHC pairs with CHC methodological queries and systemic lacunae/suggested corrective actions. -Contd.3

Table5: Discrepant CHC pairs with CHC methodological queries and systematic lacunae /corrective actions

Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Point to be made, regarding conduct of CHC process	Domain of methodological issue	Corrective systematic action
11	Thyroid	TBSRTC-I. Only cyst fluid or inadequate for opinion. Note: Large cyst may harbor a malignant focus on the side.	Nodular goiter with dominant hemorrhagic cyst.	Non-concurrence present between cytological and HPE diagnosis.	TBSRTC -I - is a large umbrella category that covers either cystic fluid only or an inadequate aspirate. In case of an older patient and haemorrhagic fluid on aspirate, a note of caution seems appropriate at times, especially if the cyst cannot be evacuated completely. However nodular goitre with a dominant haemorrhagic cyst can also present similarly on FNAC. So is this overcall on cytology, leading to the (?) non concurrence or just too large an umbrella category of TBSRTC-I needing a different perspective for CHC in this situation?	(Organisational domain-Protocol)	1.Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
12	Thyroid	TBSRTC -II. Benign thyroid pathology. Favour: Colloid goitre with cystic change	Follicular adenoma	Non-concurrence present between cytological and HPE diagnosis.	TBSRTC-II covers the entire gamut of benign thyroid lesions including follicular adenoma. As such, a diagnosis of a follicular adenoma may only be done upon confirmation of intact margins of the nodular lesion. So is it even worthwhile to report a nonconcurrence when a benign neoplasm is included in another large umbrella category that includes all the other non-neoplastic conditions, that look similar on cytology , due to lack of tissue architecture??- A known and accepted limitation of FNAC procedure? Therefore nonconcurrence in case of Thyroid FNA probably needs to be defined in a different manner??	(Organisational domain- External)	No systematic solution for this kind of situation.
13	Thyroid	Acellular smear. No opinion possible.	Multinodular goiter.	Non -concurrence of cytological and histological diagnosis.	How and whether IFO cytopathology should be considered for CHC?? Or should this situation be interpreted as a sampling error due to the known and accepted limitation of the FNAC procedure?	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.
14	Thyroid	FNAC: TBSRTC-I (Cystic fluid only)	Colloid hemorrhagic cyst	Non-concurrence present between cytological and HPE diagnosis.	TBSRTC -I - is a large umbrella category that covers either cystic fluid only or an inadequate aspirate. In case of an older patient and haemorrhagic fluid on aspirate, a note of caution seems appropriate at times, especially if the cyst cannot be evacuated completely. However nodular goitre with a dominant haemorrhagic cyst can also present similarly on FNAC. So is this overcall on cytology, leading to the (?) non concurrence or just too large an umbrella category of TBSRTC-I needing a different perspective for CHC in this situation?	1.(Organisational domain-Protocol) 2. (Technical domain - ? Equipment and Organisational domain- transfer of knowledge)	1.Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology. (Organisational domain-Protocol) 2.Reporting of FNAC of thyroid lesions too is strongly dependent on the prior ultrasonography reports.

Table 5: (?) Discrepant CHC pairs with CHC methodological queries and systemic lacunae/suggested corrective actions. -Contd.4

Table5: Discrepant CHC pairs with CHC methodological queries and systematic lacunae /corrective actions							
Sr. No..	Organ/Site	FNAC diagnosis	Histopathological diagnosis	Non-concurrence (Present /Absent)	Point to be made, regarding conduct of CHC process	Domain of methodological issue	Corrective systematic action
15	Others	No opinion possible	Lipoma	How to classify this? Concurrence or not.Since Cytological and histological diagnoses do differ.	How and whether IFO cytopathology should be considered for CHC?? Or should this situation be interpreted as a sampling error albeit due to the known and accepted limitation of the FNAC procedure?	(Organisational & Human Domain-External)	Known and accepted sampling limitations of FNAC process in the CHC process?
16	Others	No opinion possible. Please correlate clinically.	Neurilemmoma	How to classify this? Concurrence or not.Cytological and histological diagnoses differ.	How and whether IFO cytopathology should be considered for CHC?? Some lesions do not yield adequate cells for reporting on FNAC so whether this is to be considered sampling error or limitation of the FNAC procedure?	(Organisational & Human Domain-External)	Known and accepted sampling limitations of FNAC process in the CHC process?
17	Salivary gland	Likely chronic sialadenitis. However possibility of pleomorphic adenoma cannot be ruled out in the given smear appearance.	Reactive follicular hyperplasia of LNs within the salivary glands.	Non-concurrence present between cytological and HPE diagnosis.	Rare occurrence of chronic inflammation of lymph nodes within the parotid gland - causing Parotid enlargement. How to classify and interpret such situations with respect to occurence of non-concurrence and sampling errors versus just known and accepted limitation of FNAC procedure?	(Organisational domain-Protocol)	Using combination of techniques that is guidance techniques like USG for FNAC for likely better yield of sample and accessing material representative of pathology.

Table 6: Comparison of discrepancy percentages with other studies

Table 6				
Study	Organ	Specimen, No. (% of Total CHC pairs)	Overall discrepancy, No. (% of organ specific pairs)	Patient harm status - No harm %
Present study	Breast	5/45, (11 %)	5/16, (31%)	
K. Raju, et al. 2019 (24)		7/192 (25%)	7/48 (14.58%)	
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		796/6162, (12.9%)	8.30%	
Present study	LN	5/45, (11 %)	5/10, (50 %)	
K. Raju, et al. 2019 (24)		2/192, (1.04%)	2/21, (9.52%)	
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		288/6162, (4.7%)	5.90%	
Present study	Thyroid	4/45, (9%)	4/9, (44%)	
K. Raju, et al. 2019 (24)		6/192, (3.12%)	6/35 (17.14%)	
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		125/6162, (2 %) [Labelled "Endocrine"]	8%	
Present study	Salivary gland	2% (1/45)	1/3, (33%)	
K. Raju, et al. 2019 (24)		0	0	
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		29/6162, (0.5%)	3.50%	
Present study	Others (Soft tissue)	2/45, (4%)	2/7, (29%)	
K. Raju, et al. 2019 (24)		3/192 (1.52%)	3/48, (12%)	
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		345/6162, (5.6%)	7.5% (for soft tissue)	
Present study	TOTAL	17/45, (38%)		100%
K. Raju, et al. 2019 (24)		25/192 (13.02%)		59.09%
Raab, SS.; Nakhleh RE.; Arch Patho Lab Med 2005(38)		6.70%		41%

Table 7: Description of CHC discrepancies (Nonconcurrences)

TABLE 7												
Organ	Specimen, No. (% of Total CHC pairs)	Overall discrepancy, No. (% of Total organ specific pairs)	Change in categoric interpretation, (%)	Explanation	Change in same category, %	Explanation	Change in Patient information, %	Explanation	Others	Explanation
Breast	5/45, (11%)	5/16 , (31%)	1/5 (20%)	Sampling error	2/5 (40%)	Sampling error	nil	NA	2/5, (40%)	CHC methodological query, either cyto/biopsy sample-inadequate
LN	5/45, (11%)	5/10, (50 %)	2/5 (40%)	Sampling error	2/5 (40%)	Sampling error	1/5(20%)	different sites of cyto sample and biopsy sample	nil	NA
Thyroid	4/45, (9%)	4/9,(44%)	2/4 (50%)	Sampling error	1/4 (25%)	Sampling error	nil	NA	1/4, (25%)	Sampling error, cyto sample-inadequate
Salivary gland	1/45, (2%)	1/3,(33%)	nil	NA	1/1 (100%)	Sampling error	nil	NA	nil	NA
Others (Soft tissue + Bone)	2/45, (4%)	2/7, (29%)	nil	NA	nil	NA	nil	NA	2/2, (100%),	Pre-analytical (Processing) NON SAMPLING error (1/2) and Sampling error (1/2)- Inadequate FNAC
TOTAL		17/45, (38%)	5/14 , (29%, 5/17)	Sampling error	6/15, (35%, 6/17)	Sampling error	1/5, (6%. 1/17)	different sites of cyto sample and biopsy sample	5/11, (29%,5/17)	Either cyto or Biopsy sample inadequate. Sampling error or Processing error

Table 8: Comparison of salient observations regarding the CHC process, as a result of our study

CHC related observation in our study	**Author 1** Nodit, L.; Balassanian, R. et al. [2005] (21)	**Author 2** *CHC by Cytologic-Histologic Correlation Raab, SS. and Grzybicki, DM. Cancer (Cancer Cytopathol) 2011;119:293–309 (11)*	**Author 3** Crothers, B.; Jones, BA. (19) [2013]	**Author 4** Vrbin, CM; Grzybicki, DM. [2005] (32)	**Author 5** Clary, KM.; Silverman, JF. [2002] (34)	**Author 6** Nguyen LN, Crothers BA, et al. [2022](49)
Single institute study, Non gynaecological FN aspiration cytology	Single institute study, Non gynaecological cytology (Bronchial cytology)	Review and recommendations basis IOM/CAP gynaecological cytology consensus study by Vrbin, CM.; Grzybicki, DM, et al. [2005] (30)	Gynaecological cytology study. Data Sources-1) survey results from 546 US laboratories, 2) review of the literature from 1988 to 2011, 3) the College of American Pathologists Web site for consensus comments and additional survey questions.	Design.: Survey—162 American laboratories were sent a letter requesting data regarding their CHC performing methodology and variables noted during. Response frequency was 32.1%.	Single institute study. Both Gynaecological and Non-gynaecological cytology study.CHC pairs data for 26 months.	Survey, US and CAP participating international labs from 33 countries included, Sample size = 562. Non gynaecological as well as gynaecological cytology
Our study, showed that, clarity regarding when to consider a nonconcurrence as such, not just merely as a difference between the cytological and surgical pathological diagnosis is much needed. Simply noncongruent diagnoses may be a reflection of accepted limitations of sampling and/or interpretation of FNAC procedure. A more precise definition of nonconcurrence is much needed, If CHC is to be a useful quality indicator. - As, Majority of the noncongruences were a reflection of sampling issues.	1) " Sampling issues had a major role in the mi 4) Better sampling will lead to improved interpretation.sdiagnosis in 31 cases (97%)", 2) 'interpretive error was closely related to sampling error, i.e. poor sampling'. 3) It was not always possible to separate these 2 types in individual cases. 4) Better sampling will lead to improved interpretation.	1) Suggested to "Define non-correlating pairs." in order to streamline and have a standardised CHC process. 2) The definition used for a discrepant cytologic and histologic diagnosis markedly affected the discrepancy frequency. 3) Sampling errors generally are considered false-negative errors and, conceptually, are believed to be failures that occurred in the TTP steps. 4) Sampling error was considered as a valid cause of noncorrelation in women with HSIL who were followed by cervical biopsy alone. Considered as false negatives.	"discrepancies will continue to persist as long as caregivers providing the specimens remain remote from the QA process. Laboratories should consider providing adequacy statistics to caregivers, both for biopsy and Pap test procurement."	1) Most errors were caused by sampling errors. 2) Definition of discrepancy needs to be standardised, narrow vs. broad. 3) Broad definitions would result higher levels of discrepancies compared narrow definitions. 4) Defining of taxonomic references of CHC is needed and being done.	Majority of non-gynaecologic discrepancies were attributed to sampling error.	"The cause of CHC discordance was primarily sampling issues."
Methodological difficulties were encountered. As there is no standardised protocol available for non-gynaecological CHC.	Yes. Tried applying standardisation to the process, however was not possible to achieve uniformity in the different institutions that were included in the study	1) "Cytopathology practices continue to struggle with the performance of cytologic-histologic correlation (CHC) and what to do with the results." 2) "There is no standardized method for performing this comparison or reporting results," and " lack of detailed regulatory directives". 3) Laboratories also were not standardized in their performance of correlation for cytologic and histologic specimens from different anatomic sites.	"Of those labs that would like to implement standardisation, 72% would like to have guidance on the type of statistics for all laboratories to maintain, 67% seek acceptable actions for discrepancies and statistical outcomes, 61% would like to standardize the acceptable discrepancy rate between Pap test and biopsy results, and 50% seek a time-frame limit from abnormal Pap test result to cervical biopsy for correlations	Although CHC has been shown to be a useful method for error detection, the lack of uniformity in performing correlation is problematic for several reasons. 1) The absence of uniformity (e.g., the specific cytologic and histologic diagnoses that are considered discrepant) leads to difficulties in laboratories comparing data.2) The lack of standardization allows for laboratories to perform correlation with variable rigor (e.g., some laboratories simply record the discrepant diagnoses, and other laboratories review the cases prior to sign-out.3)The lack of correlation guidelines does not allow laboratories to apply "best practices" in order to use correlation data for self-improvement."	1) No methodological difficulties have been mentioned. 2) Binary division of the errors into sampling and interpretative was used. With further division into undercall and overcall.	Differing methodologies for CHC process observed and experienced a bias as a result of the same.

Table 8: Comparison of salient observations regarding the CHC process, as a result of our study, Contd. (2)

CHC related observation in our study	**Author 1** Nodit, L.; Balassanian, R. et al. [2005] (21)	**Author 2** *CHC by Cytologic-Histologic Correlation Raab, SS. and Grzybicki, DM. Cancer (Cancer Cytopathol) 2011;119:293–309 (11)*	**Author 3** Crothers, B.; Jones, BA. (19) [2013]	**Author 4** Virbin, CM; Grzybicki, DM. [2005] (32)	**Author 5** Clary, KM.; Silverman, JF. [2002] (34)	**Author 6** Nguyen LN, Crothers BA, et al. [2022](49)
What Is the Timing for Cytologic-Histologic Correlation? Prospective (Real time) or Retrospective or both	Retrospective	Mostly retrospective.	Variable. Real time correlation is better for patient care. However, Real time CHC may predispose observers to confirmation bias.	Both real time – at the time of reporting biopsy and also retrospective -for generating periodic cytopathology quality reports	Retrospective	Prospective/ Concurrent "CHC was performed -mostly at the time the corresponding surgical pathology was reviewed for reporting (70.8%; 398 of 562)" Retrospective reviews were performed mostly for Quality monitoring studies.
2 step mis match used for defining mismatch of "change of diagnosis" category	Yes	1)"The grading scale for determining the presence of a CH discrepancy changed over time; consequently, the number of detected discrepancies changed." 2) "the choice of scale in determining a non-concordance determines the number of discrepancies detected."	No, PPV (Positive predictive value) was the statistics used.	Narrower definitions such as '2 step mismatch' resulted in fewer discrepancies.	Yes.	Not mentioned
Use of LIS- Makes the process CHC easier and the absence of LIS makes CHC very difficult.	Yes	Yes	Yes	Yes	Yes	Yes
Purpose of study: Our purpose of conducting the study was based on: – "The significant point is that long term error series specific statistics and allowable margins of error can only be generated by retrospective review of long term CHC data (Centeno and Crothers 2012)	To determine causes of cytology errors using CHC and conducting RTA, to design specific practice changes for reduction of errors in the future.	"There is some consensus that CHC should be standardized to allow for comparisons across practices."	CDC grant to describe current gynaecologic cytopathology quality practices and to facilitate practice standardization, - awarded to the CAP in 2009. Study of the outcome of that effort as applied to CHC.	Variable	To study the use of cytohistologic discrepancies to investigate and reduce error. The 4 subcomponents of the study were the assessment of (1) individual pathologists' discrepancy rates, (2) specimen type discrepancy rates, (3) interobserver diagnostic variability, (4) effect on patient outcomes.	This study, based on the responses of CAP participants, surveys the penetration of the previously published standards (Crothers 2013) (19) in current CHC practices.
Whether used as clinical audit	Yes	"Consensus CHC guidelines can facilitate our interpretation of system errors and potentiate comparative studies."	At least annual data audit is advised.	Some institutes did.	Yes	Yes

Table 8: Comparison of salient observations regarding the CHC process, as a result of our study, Contd. (3)

	CHC related observation in our study	**Author 1** Nodit, L.; Balassanian, R. et al. [2005] (21)	**Author 2** *CHC by Cytologic-Histologic Correlation Raab, SS. and Grzybicki, DM. Cancer (Cancer Cytopathol) 2011;119:293–309 (11)*	**Author 3** Crothers, B.; Jones, BA. (19) [2013]	**Author 4** Vrbin, CM; Grzybicki, DM. [2005] (32)	**Author 5** Clary, KM.; Silverman, JF. [2002] (34)	**Author 6** Nguyen LN, Crothers BA, et al. [2022](49)
9	Perception: Underutilised or not.	Yes	Yes	Yes	Yes	Yes	Yes, with decline in usage over time.
10	Underutilised, due to non-standardised methodology and lack of precedent or inclusion in routine QA practices.	Underutilised, due to non-standardised methodology and lack of US.	Yes	Yes. Also lack of dedicated quality personnel and uncertainty about improving the established metrics	Yes. These issues indicate that laboratories may need to standardize the cytologic-histologic correlation processes in addition to standardizing the data collection materials.	Few objective studies of error in pathology have been performed, as a result minor variation and their effects on patient outcomes are not noted nor studied.	Yes, more so in International locations.
11	Underutilised due to non-recognition of "To err is Human"	The Pathology literature, over all approach to investigating diagnostic pitfalls implies, failures in diagnostic failures, rather than system flaws that lead to poor performance of individuals.'	Yes	Yes	Not mentioned explicitly, though acknowledged that this topic of interpretation of CHC is controversial. (Perhaps meaning sensitive topic?)	Most discussions of error in diagnostic pathology have concentrated on an individual case approach to error identification	Discordance metrics were predominantly summarized and shared in a quality improvement document -and as a summary for ongoing performance assessment.
12	RCA done	1) Yes, oriented to detection of systems related flaws, using the Toyota production systems. 2) Lists made of a) sources leading to interpretative errors and b) preanalytical and analytical factors leading sampling errors.	1) Root cause analysis using dichotomous error method- Sampling Vs interpretative, is less than optimal due to possible discordance between the opinions of original pathologist and reviewing pathologist, and because of the implied sense of blame/failure of the reporting professional. Also, this discordance between pathologists' opinion is more likely in case of discordant cases, as these are likely more challenging to interpret. 2)This system also does not allow for recognition of system related failures	Advised with follow up action for the annual audits	Yes	No, systems related root causes searched for.	Yes
13	Suggested: error reduction initiative. Yes, 1) combination of modalities, imaging and FNAC for better sampling yield via better lesion localisation and sampling specific to lesion. 2) Guidance related to clarity of CHC methodology, including updating of definition of CHC non-concurrence	Yes. Specific to error types detected. Also, that use of appropriate technologies may lead to decrease sampling errors. Also. Double viewing by different pathologists before sign out has a better impact on reducing interpretative errors	1) Suggested to design CHC to meet laboratory needs: 2) 'CHC achieves its fullest potential for monitoring system quality by evaluating the many variables affecting specimen collection, submission, processing, interpretation, and reporting through slide review'. 3) "In developing further metrics for CHC inquiry, the laboratory tailors the program to investigate potential or perceived problems."	Standardisation data gathering instruments, statistical analysis and at least annual audit of the CHC data	A list of recording 15 specific minimum expected items during CHC process was prepared and suggested as standardised CHC process. (15 minimum expected variables that could be recorded if laboratories performed cytologic-histologic correlation using this CAP Checklist as a guide for data collection.)	Yes. Individual report cards prepared for each reporting pathologist, noting individual Pathologist's Discrepancy Rates.These results could lead to implementation of educational measures to improve interpretive skills.	1)Review of microscopic slides during CHC allows for investigation of discordances, helps decrease interobserver variability, and provides invaluable learning opportunities., 2). One of the major purposes of CHC is to impact clinical care, and this is best accomplished in real time, allowing additional histologic sections and peer review to be easily performed without amending a report. 3) The strikingly low rate of CHC among the smallest institutions suggests that these organizations may benefit from receiving assistance in establishing and carrying out a program of CHC. 4) Our survey found that international laboratories have slightly lower CHC rates, and those that do CHC exercise do not perform continuous batchwise CHC analysis.

Table 8: Comparison of salient observations regarding the CHC process, as a result of our study, Contd. (4)

CHC related observation in our study	**Author 1** Nodit, L.; Balassanian, R. et al. [2005] (21)	**Author 2** *CHC by Cytologic-Histologic Correlation Raab, SS. and Grzybicki, DM. Cancer (Cancer Cytopathol) 2011;119:293–309 (11)*	**Author 3** Crothers, B.; Jones, BA. (19) [2013]	**Author 4** Vrbin, CM; Grzybicki, DM. [2005] (32)	**Author 5** Clary, KM.; Silverman, JF. [2002] (34)	**Author 6** Nguyen LN, Crothers BA, et al. [2022](49)
Whether poor processing affected cytological interpretation. Yes, at least in some cases. Combination of stains were used to overcome the processing related changes. However, the poor preparation and delayed fixation by 'pathologists in training' were difficult to overcome, since it is an integral part of teaching institute protocol.	Poor processing affected cytological interpretation, yet process related practices were not changed or repeat preparations were not asked for, in consideration of TAT, cost effectivity and the change related cooperation needed from technical staff.	1) Yes, it was acknowledged there were several latent system related preanalytical components to the interpretation /sampling errors. 2) Active Quality improvement (QI) process redesign and process improvement methods such as checklists were deployed and scoring systems for grading inadequate smears were designed and implemented, to successfully improve quality of samples and quality of reporting.	Yes, though reporting bias may affect reporting of the same.	Yes	Yes, mentioned as affecting biopsy specimen processing and interpretation.	International laboratories cited significantly more problems with process/preparation factors hindering interpretation, inappropriate/inadequate history, surgical specimens requiring reorientation, and inadequate or no sampling of the target lesion
lack of communication of relevant findings from clinical counterpart/lack of history-Affected the interpretation	Yes	Implementation of feedback systems and actions on the feedbacks from clinicians were rolled out as a part of process redesign and improved the sample quality and patient outcomes including, reduced rates of repeat FNACs.	Yes	Was part of the definition of CHC specified in this publication, - 'to correlate and explain the nonconcurrence in the light of clinical history available.'	Not mentioned	Yes
anything specific to this study	1)The biases inherent in ordering practices (by for example physicians as opposed to surgeons-depending on where the patient landed first) affected the cases that were encountered at UPMC (in the pathology dept.) and, consequently, affected the error frequencies and causes. 2)"Recommendations for error reduction could differ at other institutions because of the inherently different nature of patients who undergo bronchoscopy."	1)The " No blame model" was suggested as a new tool for root cause analysis. It avoids person specific blame. The basic theme is to plot smear quality and preparation against identification of tumour cells. 2)No-Blame Box method helps cytopathologists to understand more effectively the inter-play between specimen quality and diagnostic interpretation.3) These observations, then translate into whether error reduction strategies would focus on improving specimen quality and/ or assisting cytology personnel in improving their interpreting skills.	1) Cyto- histo. diagnoses do not have equivalent matched categories., 2) Additional CHC questions asking specific questions regarding review process – were answered by only 32/546 labs that responded to the survey originally sent to 1245 labs, (43.9%) response rate. -?? Suggesting unwillingness to share data., 3) Barriers to CH correlation studies-cytology and biopsy volumes, access to biopsy or cytology reports, practice variables and restrictions, LIS availability and variations, lack of adequate staff to dedicate to quality related efforts., 4) CHC statistical results should be tabulated, at least annually for all laboratories and evaluated for potential opportunities for improvement.5) Once problems are detected and the source identified, laboratories should implement changes in processes or policies to make permanent improvements to correct these problems.	1) Scant data exist on how the detection of discrepancies results in improved patient safety. 2) Acknowledgement of 'reporting bias', in that reporting may not be exactly a true account of how the CHC exercise is actually done.	A statistically significant association was seen between cytologic or histologic spec- imen types and discrepancy rates. Statistically, more errors than expected were seen for specimens of breast FNA and bronchial cytology, as well as brain FNA and common bile duct biopsy.	1) North American laboratories reported investigating cases in a batchlike manner while international laboratories did so less often. This may be related to availability of a supportive LIS, or to LAP requirements to compile these statistics. Alternatively, it may be due to the fact that it is a federal mandate to do this in the United States, compared to the other countries where it is simply done for quality assurance. 2) The survey shows an overall decline of correlation rates in gynaecologic specimens when compared to the prior survey. The underlying etiology for this small but notable decline is unclear. This will be an interesting topic for future studies.

FIGURES:

Fig 1: Melanoma, lack of clinical history of foot ulcer, localised deposits of melanoma from enlarged inguinal LN aspirate, led to melanoma diagnosis

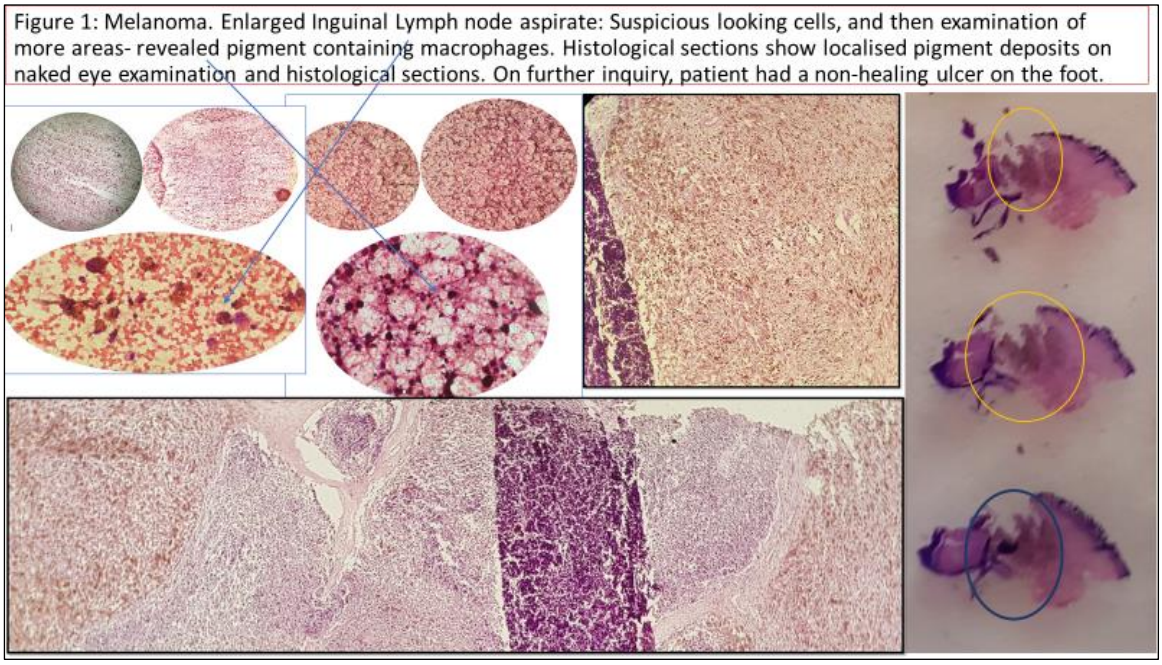


Fig 2: Carcinoma Breast, with isolated LN deposit, missed as sampling deficit on FNAC

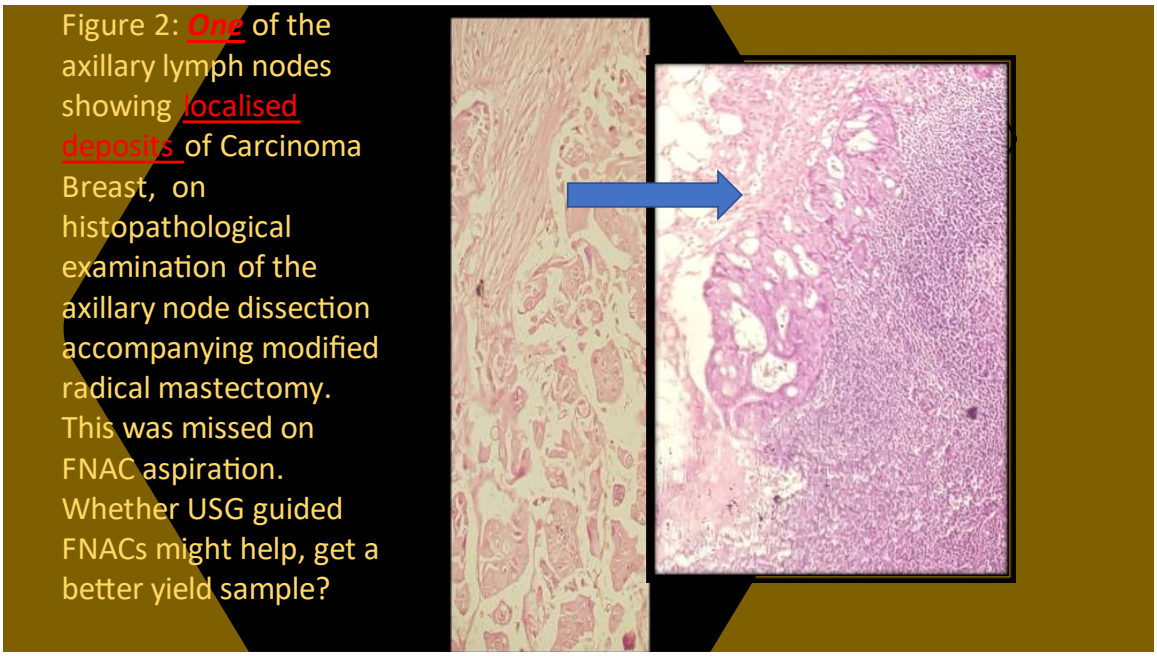


Fig 3: Illustration of sampling difficulty in fibroadenoma breast, with fibrous areas leading to acellular areas on aspirate smears and cellular clumps from the adenomatous portions.

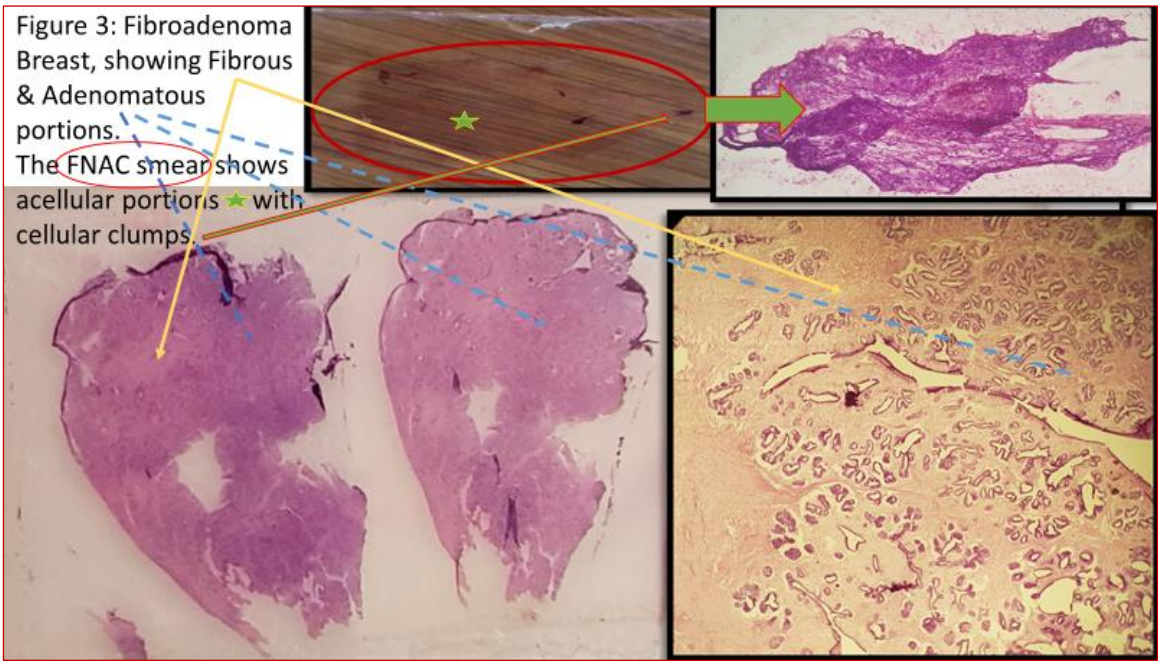


Fig 4: Thyroid cyst, Sampling and CHC interpretation difficulty

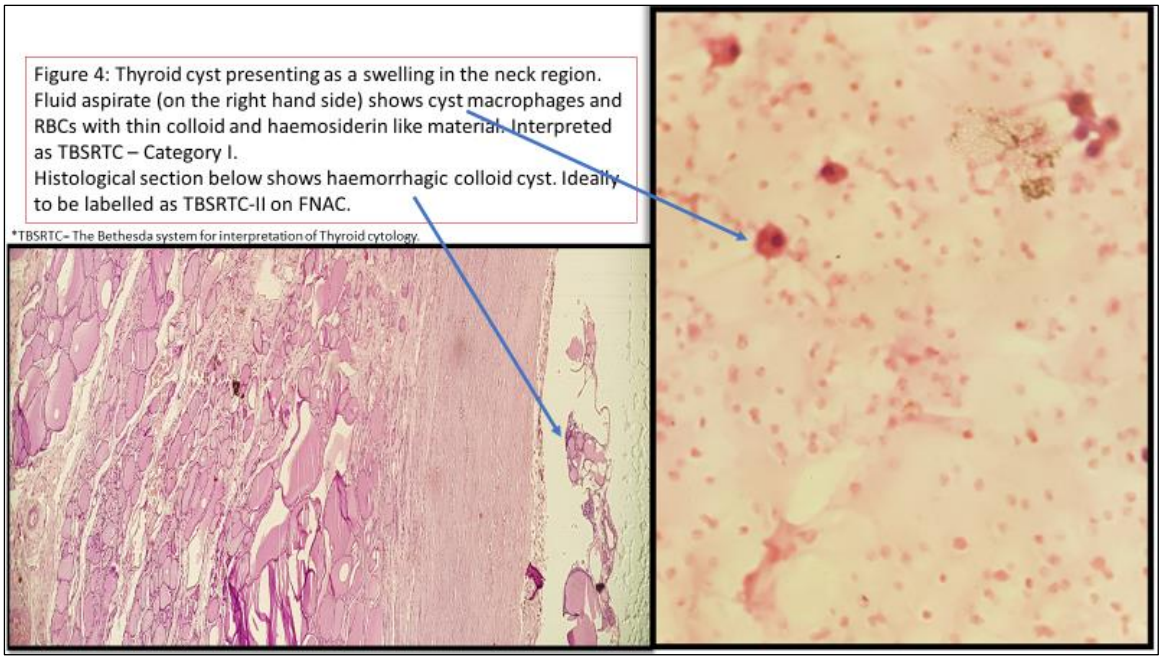


Fig 5: Lipoma, processing of aspirate smears leads to acellular smears, inadequate for diagnosis by definition.

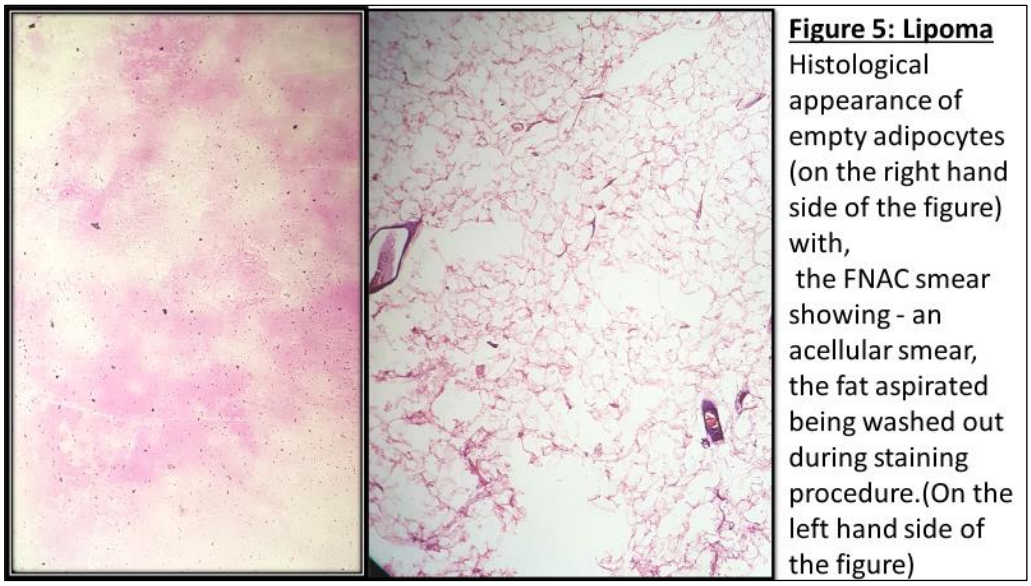
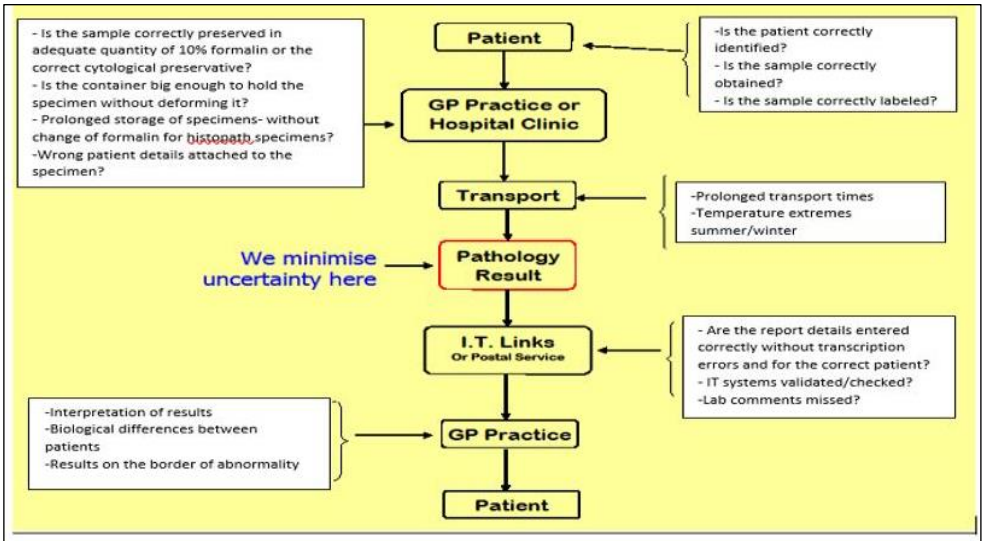


Figure 5: Lipoma Histological appearance of empty adipocytes (on the right hand side of the figure) with, the FNAC smear showing - an acellular smear, the fat aspirated being washed out during staining procedure.(On the left hand side of the figure)

Fig 6: Sources of Pre and Post analytical errors



Implementation of quality initiatives in a clinical laboratory is a complex process, as it is at least partly dependent on collection done on the clinical side. This is the major part of the pre-analytical portion of laboratory quality control. After this, the sample enters a laboratory and the quality initiatives here are again subdivided into pre-analytical, analytical and post-analytical. Communication at all the handover points in between the subdivisions as well as the communication regarding the background investigations, clinical findings and imaging investigation findings are important in order to ensure optimum reporting of all pathology samples.

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Supporting information

Note 1: There are three ways in which CHC may be conducted [19],

1) Review of both cytology and surgical pathology slides by two independent reviewers.
2) Review of only cytology slides in view of discordant surgical pathology diagnosis.
3) only paper-based review of the cytology as well as surgical pathology diagnosis.

Note 2: The essential minimum variables required for CHC analysis per, Table 1 in Raab, *et al*. 2011[27, 38]

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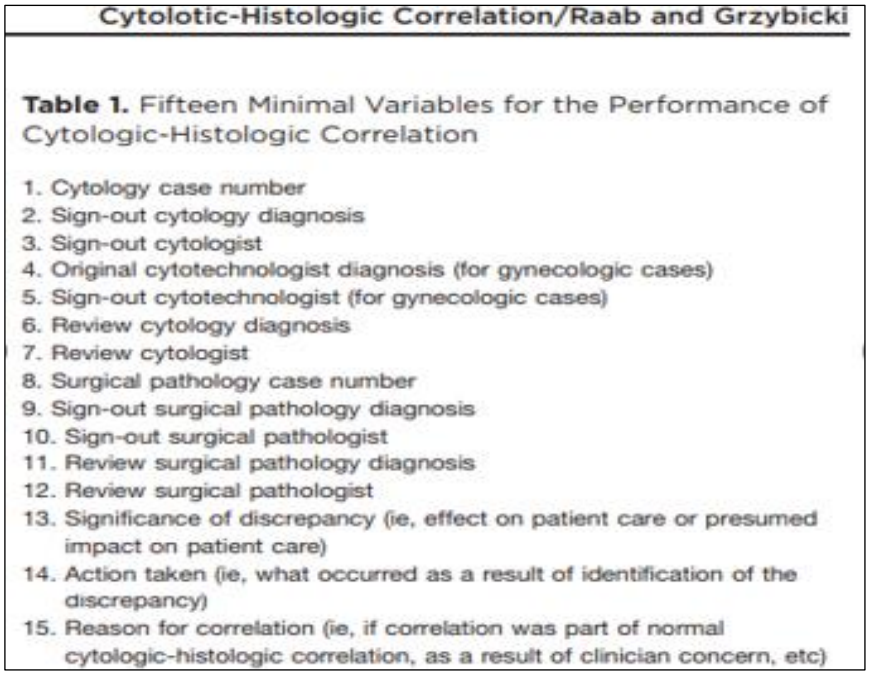

Cytolotic-Histologic Correlation/Raab and Grzybicki

Table 1. Fifteen Minimal Variables for the Performance of Cytologic-Histologic Correlation

1. Cytology case number
2. Sign-out cytology diagnosis
3. Sign-out cytologist
4. Original cytotechnologist diagnosis (for gynecologic cases)
5. Sign-out cytotechnologist (for gynecologic cases)
6. Review cytology diagnosis
7. Review cytologist
8. Surgical pathology case number
9. Sign-out surgical pathology diagnosis
10. Sign-out surgical pathologist
11. Review surgical pathology diagnosis
12. Review surgical pathologist
13. Significance of discrepancy (ie, effect on patient care or presumed impact on patient care)
14. Action taken (ie, what occurred as a result of identification of the discrepancy)
15. Reason for correlation (ie, if correlation was part of normal cytologic-histologic correlation, as a result of clinician concern, etc)

Note 3: For definition of a discrepant CHC pair and assigning the type of discrepancy for each discrepant pair, we used the definitions given in Raab & Nakhleh *et al*. [38],in table 1,page 460. This is, as given below:

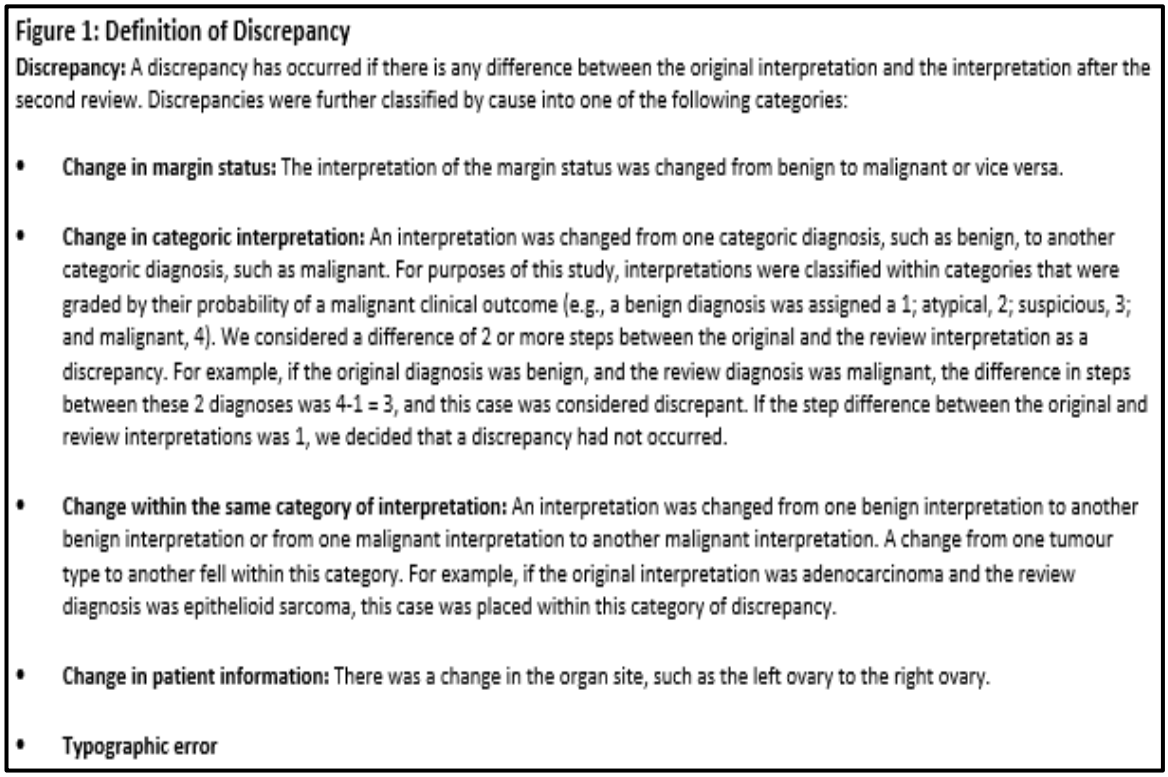

Figure 1: Definition of Discrepancy

Discrepancy: A discrepancy has occurred if there is any difference between the original interpretation and the interpretation after the second review. Discrepancies were further classified by cause into one of the following categories:

- **Change in margin status:** The interpretation of the margin status was changed from benign to malignant or vice versa.
- **Change in categoric interpretation:** An interpretation was changed from one categoric diagnosis, such as benign, to another categoric diagnosis, such as malignant. For purposes of this study, interpretations were classified within categories that were graded by their probability of a malignant clinical outcome (e.g., a benign diagnosis was assigned a 1; atypical, 2; suspicious, 3; and malignant, 4). We considered a difference of 2 or more steps between the original and the review interpretation as a discrepancy. For example, if the original diagnosis was benign, and the review diagnosis was malignant, the difference in steps between these 2 diagnoses was 4-1 = 3, and this case was considered discrepant. If the step difference between the original and review interpretations was 1, we decided that a discrepancy had not occurred.
- **Change within the same category of interpretation:** An interpretation was changed from one benign interpretation to another benign interpretation or from one malignant interpretation to another malignant interpretation. A change from one tumour type to another fell within this category. For example, if the original interpretation was adenocarcinoma and the review diagnosis was epithelioid sarcoma, this case was placed within this category of discrepancy.
- **Change in patient information:** There was a change in the organ site, such as the left ovary to the right ovary.
- **Typographic error**

Note 4: Eindhoven model, as given in table 4, page 340, Raab, Grzybicki [27].

Table 4. Root Causes of Error Using the Eindhoven Classification Model

Code	Category	Definition
Errors that result from underlying system failures		
Latent errors		
Technical: Physical items such as equipment, physical installations, software, materials, labels and forms		
TEX	External	Failures beyond the control of the investigating organization
TD	Design	Inadequate design of equipment, software, or materials; can apply to the design of workspace software packages, forms, and label design
TC	Construction	Designs that were not constructed properly; examples include incorrect set-up and installation of equipment in an inaccessible area
TM	Materials	Material defects found; examples could be the weld seams on blood bags, defects in label adhesive or ink smears on preprinted labels or forms
Organizational		
OEX	External	Failures beyond the control and responsibility of the investigation organization
OP	Protocols/Procedures	Quality and availability of protocols that are too complicated, inaccurate, unrealistic, absent or poorly presented
OK	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or site-specific knowledge or information is transferred to all new or inexperienced staff
OM	Management priorities	Internal management decisions in which safety is relegated to an inferior position when there are conflicting demands or objectives; this is a conflict between production needs and safety
OC	Culture	A collective approach, and its attendant modes, to safety and risk rather than the behavior of just one individual; groups might establish their own modes of function as opposed to following prescribed methods
Active errors		Errors or failures that result from human behavior
HEX	External	Failures originating beyond the control and responsibility of the investigation organization
Knowledge-based behaviors		
HKK		The inability of an individual to apply his or her existing knowledge to a novel situation
Rule-based behaviors		
HRQ	Qualifications	The incorrect fit between an individual's qualification, training, or education and a particular task
HRC	Coordination	A lack of task coordination within a health care team in an organization
HRV	Verification	The incorrect or incomplete assessment of a situation, including related conditions of the patient/donor and materials to be used before beginning the task
HRI	Intervention	Failures that result from faulty task planning and execution; this would be selecting the wrong rule or protocol (planning) or executing the protocol incorrectly (execution)
HRM	Monitoring	Failures that result from monitoring of process or patient status
Skill-based behaviors		
HSS	Slip	Failures in the performance of highly developed skills
HST	Tripping	Failures in whole-body movement; these errors are often referred to as "slipping, tripping, or falling"
Other factors		
PRF	Patient-related factors	Failures related to patient/donor characteristics or actions that are beyond the control of the health professional team and influence treatment
Unclassifiable		Failures that cannor be classified in any of the current categories

Note 5. Method used for designating error induced patient harm status, we used the definition given in Raab & Grzybicki *et al*. [27] in table 5,page 302. This is as given below:

Table 5. Error Clinical Severity Categories

- No harm

The clinician acted regardless of an erroneous diagnosis
Example: A patient had a lung mass, and the clinician performed a bronchial washing and biopsy at the same time; the washing was diagnosed as malignant, and the biopsy was diagnosed as benign (sampling error); the clinician acted on the malignant cytology diagnosis regardless of the surgical diagnosis

- Near miss

The clinician intervened before harm occurred or the clinician did not act on an erroneous diagnosis
Example: A patient had a lung mass, and a bronchoalveolar lavage was obtained and diagnosed as benign (sampling error); the surgeon proceeded
with a therapeutic surgical procedure, because the radiologic evidence supported the diagnosis of malignancy; the diagnosis on the surgical specimen was malignant

- Significant event

- Minimal harm (grade 1)
  a. Unnecessary, noninvasive further diagnostic test(s) performed (eg, blood test, noninvasive radiologic examination)
  b. Delay in diagnosis or therapy (</ =) 6 mo
  c. Minor morbidity because of (otherwise) unnecessary further diagnostic effort(s) or therapy (eg, bronchoscopy) predicated on presence of (unjustified) diagnosis
- Moderate harm (grade 2)
  a. Unnecessary, invasive further diagnostic test(s) (e.g. tissue biopsy, re-excision, angiogram, radionuclide study, colonoscopy)
  b. Delay in diagnosis or therapy for (>/=) 6 month duration
  c. Major morbidity lasting (>/=) 6 mo because of (otherwise) unnecessary further diagnostic efforts or therapy predicated on the presence of (unjustified) diagnosis.
- Severe harm (grade 3)
  Loss of life, limb, or other body part or long-lasting morbidity (>6 months)