Postanalytical external quality assurance in automated haematology- experiences from Scandinavia , cooperation between NOKLUS/NKK and EQUALIS (Norway & Sweden)

What is postanalytical quality assurance in automated haematology?

Quality assurance of postanalytical factors like :

- interpretion of results, histograms and scatterplots
- correct actions taken to verify results
- reporting the results back to the doctor /ward / department

Why is postanalytical quality assurance important ?

- **Prevent that erronous results are being reported**
- **To catch up and be aware of the information that might be important for the diagnose and use the information to the best of the patient**

Reasons to start an external post-analytical quality assessment scheme

- Many years experiences from ”user-meetings” shows that the analytical part is well taken care of in the majority of laboratories , while many users have problems both with the interpretetion of the results / plots and performing the correct actions to get a correct result.
- As external quality assurance it might have an educational effect
  - internal discusson about the results you are going to report
  - compare your inrepretations and actions to other laboratories

Postanalytical quality assurance survey in Norway&Sweden ; pilotproject May 2000, 1th ordinary survey december 2001

- NOKLUS /NKK/ EQUALIS did a pilot project in May 2000 ,trying to find out how Norwegian and Swedish laboratories handled the information from the automated haematology instruments, what corrective actions this information would cause and how the results were reported.
- 30 Norwegian and 28 Swedish laboratories participated in the pilotproject
- The participating laboratories were chosen among those who were using CELLDYN 4000,Coulter (STKS, GENS, MAXM) or Bayer instruments (ADVIA 120, H*series)

Postanalytical quality assurance schemes in Norway&Sweden ; pilotproject May 2000, 1th ordinary scheme december 2001

- In the pilotproject, plots from 3 cases were sent out
  - MDS, AML & MNI
- The pilotproject showed major differencies between the laboratories
- The pilotproject showed a need for standardisation.

Scheme for the survey (pilotproject)

- 3 different bloodsamples were analysed in Coulter STKS, Bayer H*2 and CELLDYN 4000 at the University hospital in Trondheim within the same day
- Plots from the 3 bloodsamples were submitted to 58 laboratories (20 Coulter,20 Bayer,18 Celldyn)
- Each lab. received plots from the instrument they were using as their routine instrument
- Some clinical information about the patients and relevant questions about the results/plots, were given in the questionnaire

Questionnaire

- Comments to the survey ?
- 1. Would you accept the requested parameters as they are reported in the instrument print-out ?

2. Would you report back other parameters than those who are requested -numbers /flags / interpretive report ?

3.What actions would you take before reporting the result ?

4.How would you report the results back to the dept./dr. ?

Main differencies between laboratories in Norway and Sweden in "following-up" cases in the pilotproject-MDS,AML,MNI

Corrective actions	Norwegian labs.	Swedish labs.
Checking for PLT aggregates in a amear	50 %	10 %
Manual count of WBC and PLT	36 – 65 %	65 – 100 %
Manual DIFF	23 – 32 %	64 – 100 %
Reporting flags/"interpretive report"	30 %	10 %
Typing in textcomments to comment the results	75 %	25 %
Additional requests made by the lab as follow up.. (CRP,LDH,Mononucleosis	18 – 77 %	0 – 35 %

1th ordinary survey December 2001

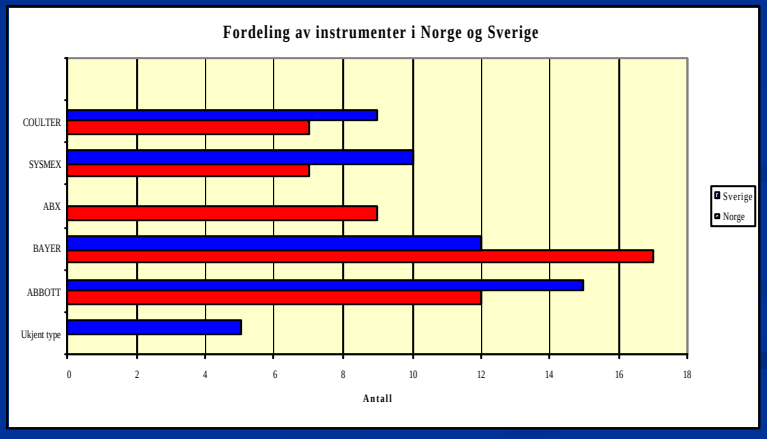
- Plot were sent to all Norwgian (71) and Swedish(68) laboratories wich had an automated 5-part DIFF instrument within the instrument groups:
  - ABBOTT (CELLDYN 4000)
  - ABX (ARGOS,VEGA,PENTRA)
  - BAYER (ADVIA 120 , H*1,2,3)
  - Coulter (STKS,GENS,MAXM)
  - SYSMEX (NE 8000,SE9000&9500,SF3000 &XE2100)
- Plot from a bloodsample of a patient suffering from CLL was sent to the participating laboratories.

Scheme for the survey in December 2001

- The bloodsample from the patient with CLL, was analysed within the same day in CELL DYN 4000,ABX Pentra 120, ADVIA 120 and Coulter STKS at the University Hospital in Trondheim (St.Olav)
- The same bloodsample was sent with courier mail to a hospital in OSLO (SIA) to be analysed in SYSMEX XE2100 & SE9000 within the same day
- Ech lab received a plot from the instrument they were using as their routine instrument.
- Some clinical information about the patients and relevant questions about the results/plots, were given in the questionnaire

Overview of received results and distribution of instruments in Norway and Sweden

- Received answers : 68% from Norwegian and and 76 % from Swedish laboratories



Questionnaire

- Comments to the survey ?
- Clinical information about the patient and information about which parameters that is requested

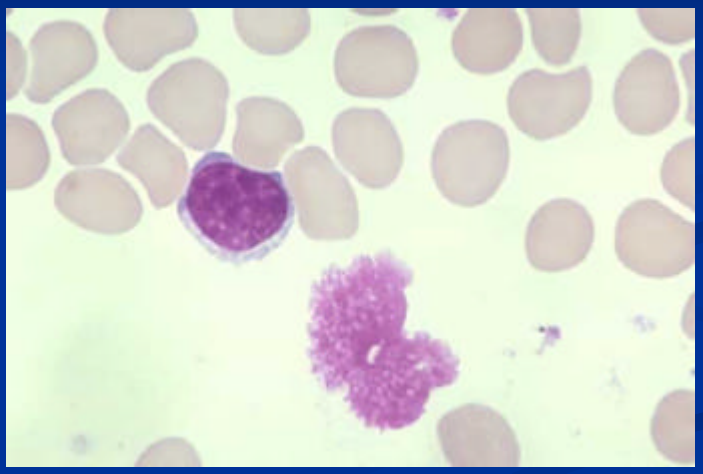
1. Which parameters or flags will you report back to the dept./doctor?
2. What corrective actions/further ivestigation will be done before reporting the result ?
3. .How would you report the results back to the dept./dr. ?

The case and results after analysis in the hospital lab.

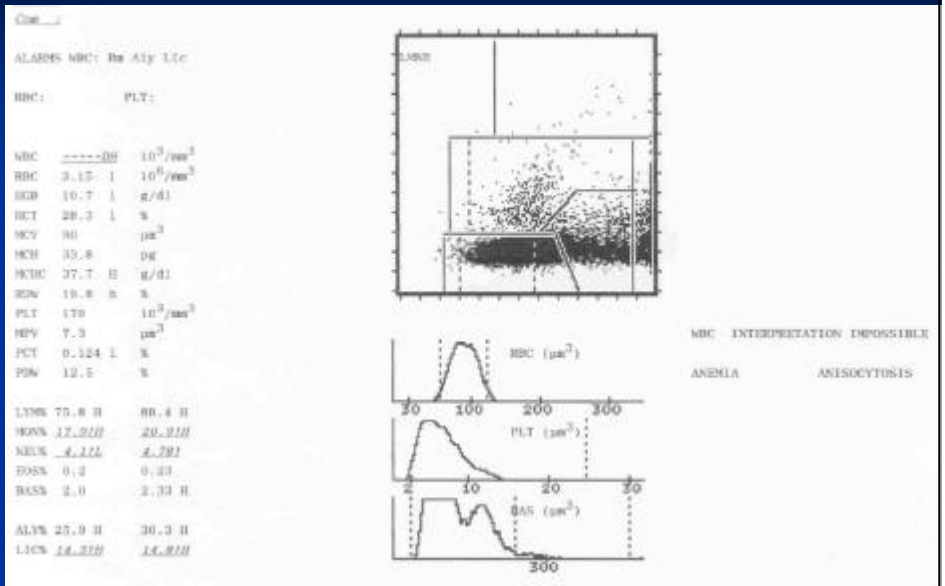
- The bloodsample was submitted to the hospital lab. from primary health care (GP)
- The bloodsample was from a man born in 1930, he visited the doctor because he felt tired. Hgb was analysed at the GP's office (not known)
- Only WBC is requestet from the GP

- Results after being analysed in the hospital lab.:
- WBC:142,9 x 10^9/l
- Pronounced lymphocytosis (about 90%) with some atypical lymphocytes (fragile cells/Gumprecht's shadows)
- Hgb : 9,5 g/dl
- PLT count : normal
- The scatterplot is typical for CLL.

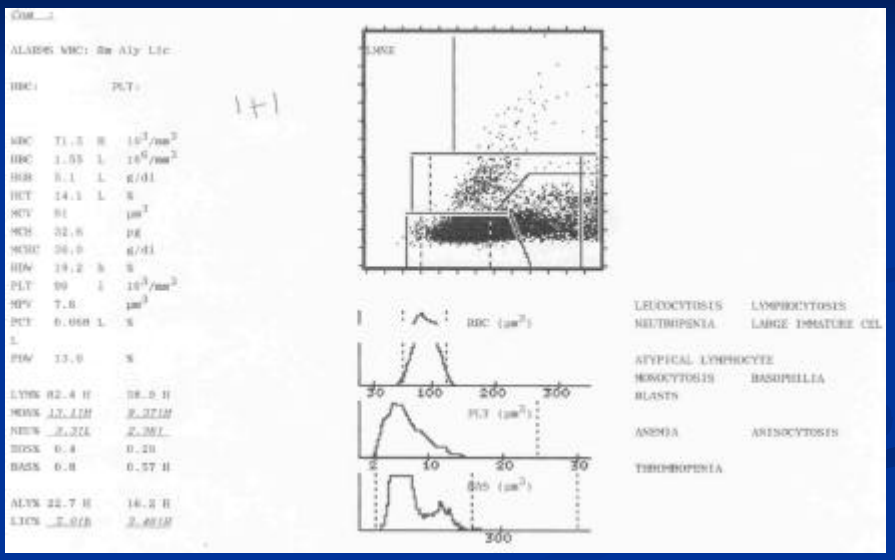
CLL-cronic lymfatic leukemia



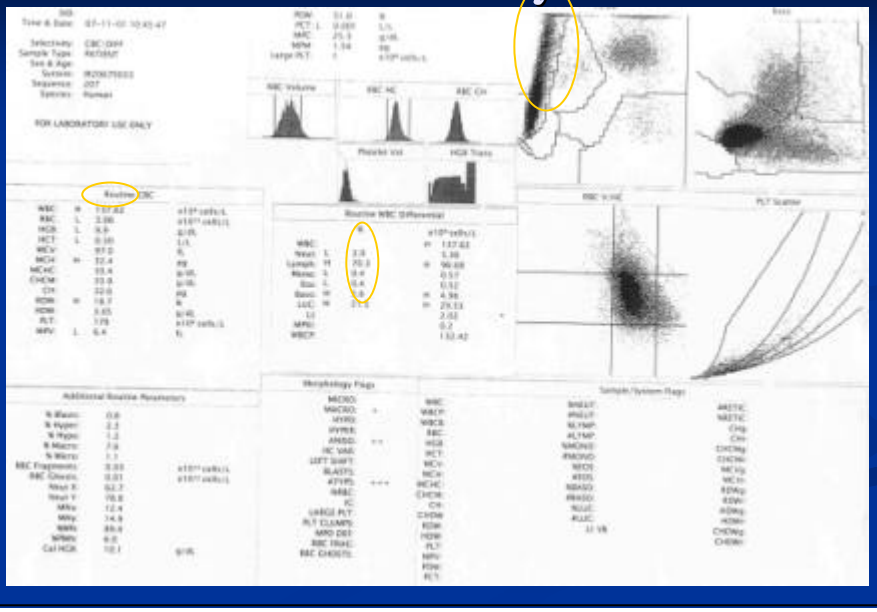
PLOT-ABX



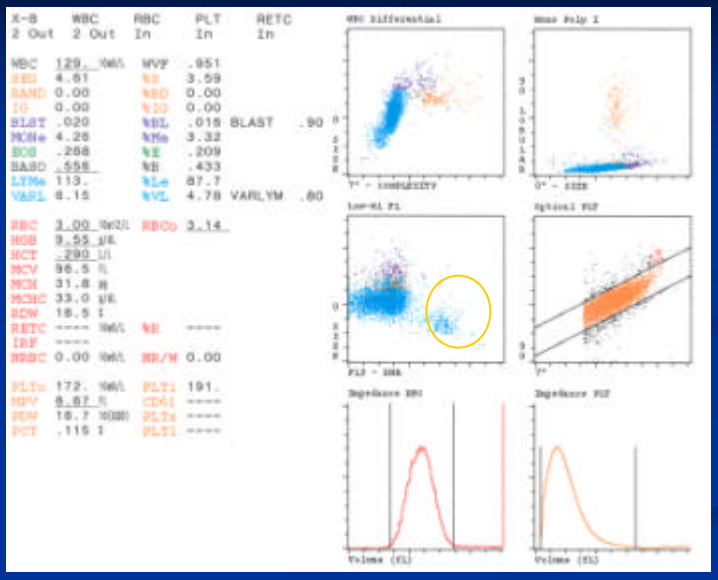
Plot ABX- prøve fortynnet 1+1



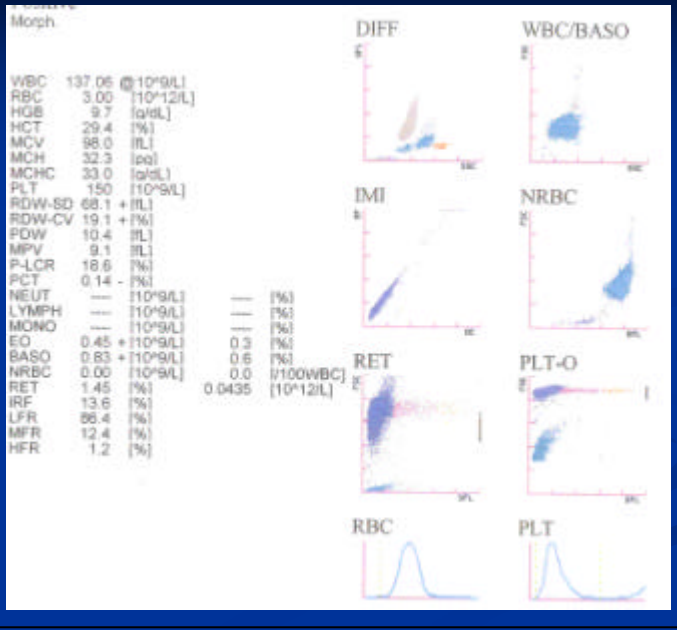
Plot - Bayer



Plot – ABBOT



Plot-Sysmex XE 2100



Results

The parameters which the lab.will report from their instruments.	Swedish laboratories	Norwegian laboratories
WBC (requested)	92 %	89 %
RBC	40 %	23 %
Hgb	54 %	60 %
EVF (HCT)	42 %	26 %
MCV	39 %	21 %
MCH	33 %	19 %
MCHC	29 %	17 %
PLT	44 %	36 %
5-part DIFF	19 %	57 %
Alarm/flag from plot	8 %	21 %
Comment to the dept./dr. based on flags	19 %	32 %
Textcomments filling in/describing the findings	31 %	70 %

Comparison of the different "instrument"user groups that would report an automated DIFF from this patient (CLL) 57% of Norwegian lab., 19% of Swedish lab.

Type of instrument	% within the instrumentgroup that would report an automated DIFF
Bayer	61 %
ABX	44 %
Coulter	35 %
ABBOTT	24 %
SYSMEX	24 %

Comments to the results

- In Sweden: mer usual to report hematogram (WBC,RBC,Hgb.MCV) when only one parameter is requested. Twice as many Swedish as Norwegian laboratories report these parameters.
- Hgb – just a few of hose who would report Hgb commented that they would correct the Hgb due to leucocytosis before reportting the answer.
  - CELLDYN 4000 and SYSMEX XE&SE reported "nearly" correct result and calculated Hgb from Bayer.
- Flags/alarms
  - -21% norwegian and 8% swedish lab. Would have reported
    - ATYPICAL LYMFO
    - ANISOCYTOSIS,Makrocytosis
- Example of comments from Norwegian lab.:. (32%):
  - "smear made, will be examinedt","DIFFrrequested in additiont", "Lymphocytosis","Typical lymphocytes are present","Result is not within normal range", "blasts" , "leukocytosis/neutropenia"
- Example of comment from Swedish lab.: (19%):
  - "manual DIFF will be done", "the result is phoned"

Will any corrective actions be done before verifying the results?

Corrective actions	Swedish lab.	Norwegian lab.
Reanalysing the sample in the same instr.	67 %	68 %
Reanalysing the sample in instrument with different methods/measuring principles	**12 %**	**40 %**
Checking if bloodsamples from this patient has been analysed in the lab. before	96 %	94 %
Making a bloodsmear	79 %	79 %
Reviewing the smear	50 %	53 %
The smear is reviewd by a medical techn.	67 %	36 %
The smear is reviewed by a doctor in the lab	**4 %**	**60 %**

Will any corrective actions be done before verifying the results?

Corrective actions	Swedish lab.	Norwegian lab.
Review/estimate the number of PLT in a smear	8 %	11 %
Counting of PLT in microscope	10 %	2 %
Counting of WBC in microscope	**27 %**	0 %
Manual differential count-100 cells	15 %	30 %
Manual differential count-200 cells	58 %	**0** %
Discussing the results /scatterplots with a doctor in the lab.	2 %	36 %
Discussing the results/scatterplots with a pathologist/haematologist	12 %	**47%**
Additional requests (LDH,CRP,……)	4 %	49 %

How will the results be reported back to the dept./doctor ?

Ways of reporting the results	Swedish lab.	Norweg. lab
The results are being transmitted ON-line from the instrument to the labdata system, then a lab.report is generated from the labdata system	65 %	77 %
Online: instr.-> lab.dataystem->electronic patient journal	75 %	70 %
Plot/printout from the instrument is sent to the ward/dr., the ward /dr. has to interprete the results themselves	8 %	17 %
The results are being accomplished in the lab.data report with text comments like :"Left shift","The bloodpicture is consistant with CLL", "The result has been verified with manual PLT count…"	27 %	64 %
The results are reported to doctor/ward by phone	81 %	89 %
The results are reported in another way	8 %	25 %

Comments to the results

- In Norway:
  - 34 of 48 laboratories would have accomplished the final report with text comments
  - 5 of 48 laboratories would have given a ”diagnostic comment”: ”The bloodpicture might be consistant with CLL /leucemia”
  - 16 of 48 lab. would have described the findings in the bloodsmear
- In Sweden:
  - 14 of 52 laboratoriesr would have accomplished the final report with text comments
  - 3 of 52 laboratories would have commented findings in the bloodsmear,the degree of maturuty of the cells, morphological findings – no diagnostic comments.
  - Other text comments would be like :” Manual DIFF is performed..”Verified by manual count”.
- Both in Norway and Sweden it is most common that the medical technologists are ringing out pathological findings/results.
- The way of reporting the results except from ON-line -> labdata system or to electronic patient journal : written letters, separate report forms, separate report forms for bloodsmears , fax (Sweden : 3 lab)

Summary

- The survey has showed that postanalytical quality assurance is important to make sure that correct results are beeing reported.
- We observe the same large differences now ,compared to the pilotproject, between the laboratories in what results they report and what correct actions they make before reporting them.
- We do still observe a ”culturel difference” between swedish and norwegian laboratories.
- External postanalytical quality assurance makes us aware of the different routines and hopefully it might have an educational effect.