-

European Partnership for Supervisory Organisations in Health Services and Social Care

EPSO EFFECTIVENESS WORKING GROUP MEETING (first meeting by invitation of the Norwegian Board of Health Supervision)

10:00-16:00 (local time) Wednesday 11 May in Oslo, Norway

Location : Helsetilsynet (The Norwegian Board of Health Supervision), Calmeyers gate 1, Oslo

Participants : Riitta Aejmelaeus-Chair: (FI), Hanna Ahonen (FI), Einar Hovlid- host (NOR), Geir-Sverre Braut (NOR)- (not present), Ian Leistikow (NL), Ester Deursen (NL), Klas Öberg (SWE), Lena Weilandt (SWE), Anna Beckett (UK), Emily Hutchison (UK), Lena Graversen (DK) , Jooske Vos, Mari Murel, notes, (EPSO)

EPSO contacts: Jooske Vos jmvos@eurinspect.nl +31-6-13163557 (mobile)/**Mari Murel** mmurel@epsonet.eu + 31-6-31684526 (mobile)

Programme

Presenting and discussing the cases from the various countries.

All the member organisations has been asked , considering the cases, to prepare:

- A short analysis of the problem in your country;
- A description of the method/methods chosen to solve the problem;
- A description of the results(if results are available): what was effective, what was not effective?;
- Questions to discuss or to answer by the working group.

Presentations are available at the website of EPSO : http://www.epsonet.eu/oslo-11-05-16.html

Jooske (Vos), EPSO introduction

This working group was actually started by Einar during our last EPSO conference in Helsinki, where effectiveness was one of our topics. There were lot of discussions and then Einar suggested that why not to organise a separate meeting to go further with that apparently important topic. Therefore we did an inventory who would be the most interested to participate and come together as we are now in Oslo. Riitta, our Finnish colleague is chairing this working group and meeting. We hope that this will be a start of continuous working group, who can time-to-time if necessary come together if possible, but most of all continue working using electronic communication.

Riitta (Aejmelaeus) welcomes everybody and introduces the topic Effectiveness, the cases and the theory behind it. First we hear all the cases, then discuss it further and decide how to proceed.

-

Norway, Einar Hovlid, The Norwegian Board of Health Supervision (Helsetilsynet);

As regulators we are already facing the expectations from the public, that what we too should be effective and it would be probably even more higher pressure in the future to document what we do and to show that it has improved effect on the quality and safety of the healthcare. Glad we all came together and are discussing such an important topic on the forefront.

He is presenting the case from Norway, how they use the clinical data for the inspections. The reason they choose this topic is that they think that perceived clinical relevance of inspection findings is important for engage people and improvement activities following the inspection. To present both to the staff and also to the managers.

It can be hard to find an relevant data and also to collect it and use it in an useful way and to systematise it and to display it. Will present the 'test' case, what is smth. new, at least in Norway, to collect data of sepsis detection and treatment. Will show the case and what they have done:

They identified key indicators for the clinical process of detection and treatment of sepsis. For that international research was used and sepsis campaign from England this year. Few examples:

Time to triage- that is important to get a good start;

Time to (first) assessment by physician;

Time to blood samples;

Time to treatment with antibiotics.

Those are all relevant clinical indicators what tell us about the quality of care what is provided. Drawback is that those indicators are not regularly available in a register, they have to collect them themselves as part of the inspection and that is a lot of work. They use a form as inspectors go through the patient records, collect data 2x33 patient records and it is all done in a systematic way. Next step is to transfer the data to an excel file, what they have created with all kind of formulas to auto-generate diagrams. They use the same data also for the research purposes, but this is particularly meant for the inspections. For example we can see by the time, when triage is done (it should be below 15 min), that for a couple of patients triage is done later than 15 minutes. It is very easy to present it to medical personnel and to managers, it is very easy to read it and they are used with that sort of diagrams. Then they see that this is not good and they cannot go on like that. Sometimes missing data can be a problem. They also do more sophisticated analyses to sort of help hospitals to do that kind of judgement.

Then they go out of the excels and start conversation i.e. they see that there were 30 patients getting antibiotics later than 2 hours, so they expect that that they have assessment by doctors within the appropriate time period; they should have complete sets of vital signs taken, blood samples taken within 30 minutes and there should be proper surveillance regime in case something deteriorates. And then they see that only for 2 patients out of those 3o patients (who received antibiotics later than 2 hours) have this process been followed. It seems that the reason for that is not that you have an good process to take care of the patients, but that you actively do smth and you see if they really need antibiotics, as this does not seem to be the case- most of those patient won't receive what is expected. And again this will communicate well with the clinicians. They understand that there clinical processes are not as good as they thought they were.

-

The presented data is made up, but as they have made 4 inspections/ data collections like this, it seems that data could be like this, unfortunate from the patient perspective.

Lena W –what is the criteria for sepsis?

Einar-They use an old criteria and the prevalence is up to 3-5% of all hospitalised patients. So this is a big patient population and probably the biggest patient safety hazards that could be addressed and done smth with. Internationally it is claimed that sepsis is a biggest avoidable patient safety issue.

Riitta – if the diagnoses is delayed, have you compared it with the hospitalisation numbers and the mortality rates?

Einar-They do it during the research process, but they cannot do it actually during the inspection of one hospital, because to look into mortality rates, you need a huge amount of data, which you cannot collect with one inspection. But in the national level they do it to see if all the inspected hospitals will improve and hopefully their mortality rate will go down.

Riitta- how about the length of the hospital stay? As it is said to be one of the quality indicators.

Einar- Yes, they might try to look into that also, but it is not very sensitive quality indicator, because there is so many things that can influence the length of stay, like capacity etc. But yes, it is smth they are thinking about.

All together by combining data and displaying it, they can prescribe what is the picture of the clinical data and how the clinical processes are taking care of in their hospital. Their experience is that by systematically collecting clinical data, they can use it both for inspection itself but also for research purposes, where they can see what happens and follow the development. This shown way of presenting the clinical data is easily understandable for the hospitals, it communicates well, which adds to credibility and engagement of the inspection findings and people are more likely to be engaged and to think that they need to improve this instead of just writing things out.

Emily- What extent hospitals might collect that data already and look at that the way you do?

Einar- What they have found so far is that the first 4 hospitals that they inspected, did not do it and they have had expect them that they should do it. They also do interviews as part of the research project and the managers say that they know they should do it, but for various reasons they do not – they do not have the competence or the time etc. and even if they collect them, they have hard time analysing them and putting them together and to find out what they really mean to them and how do they add up. So the aim in the long run is that the hospitals should do it themselves in the future. The best probably do, but most do not.

Emily- this is now part of the research project, but if it is successful would you consider to make it a part of your inspections?

Einar- yes, they have already discussed this and for the sepsis it is easily applied, because you have so many things you can measure, but they will try to use this method for other type of inspections as well.

Ian- It will be interesting to see if hospitals would start to collect this data knowing that you are going to come to inspect them.

Einar- What they do is that they go to hospital to collect the set of data before the measurement and then they tell them, that they will come back after 8 months, they will collect the same data, this

is what they look at, this is what you need to improve and what they hope is that they start to trigger hospitals to collect data of themselves. How it should be.

Ian- the other hospitals, who hasn't been inspected yet, they will probably talk to those hospitals, who you have already visited and will start to collect the data even more as you proceed your research.

Einar- yes and because they have baseline measurement and they will do interviews before and as part of the research they can detect that.

Ian-And that could be one of the effects?

Einar- Yes, that can, hopefully, but the hospitals are slow.

Jooske- what is your idea- did they start doing it?

Einar – too early to say, they started 1 month ago.

Lena G –Did the hospitals became more aware what they did wrong? Not only to collect data, but to improve the situation.

Einar- yes, it helps many things. First of all it helps inspectors. Because what they know from experience and also from the research is that the people doing the inspections will have a hard time making use of the data. So it helps the inspectors to focus and it adds credibility to their findings, its more easily understandable. They hope that, they do not know yet, but so far experience tells that it is more understandable to the hospitals what they need to do and fix. And they will collect the data to see the development if they actually will do it with new measurement after 8 months.

Anna – Do you benchmark different regions or hospitals and actually say to the hospitals that you are doing much better or worse than the others?

Einar – they could do that, but the problem is the data quality as in some hospitals the patient records are not as well as they should be, so there would be lot of data missing. But they do benchmarking to some extent.

Lena W- Are you going to follow this baseline research after time?

Einar- We have a baseline measurement for all the hospitals we are going to inspect, 24 hospitals in Norway. They have baseline measurement for September 2015 and then they do measurement before the inspections (stepped wedge design). They roll up inspections 2 per month, so the inspection will be rolled during entire year. They measure before the inspection and 8 months after the inspection. By doing it this way they are able to compare it between before and after measurements in a sophisticated way. And they can also prepare it regionally (Oslo –North). And they do interviews as part of the research project with the inspection teams with the hospitals, before and after the inspections. To find out what they do and do they start doing it what they suggest they should do and what inspectors think and if those suggestions help them.

Klas- Likes the way they (Norway) concentrate on quality and processes. They try to do the same in Sweden and have internal discussions within the inspectorate if that is really what they should do and what if the hospitals do not follow the recommendations and what details you inspect, quality of inspections etc . He really thinks that this is right way to go and he is struggling to convince his organisation that this is the right way. Do you have same discussions within the organisation in Norway?

-

Einar- there is a discussions how much they should focus on clinical processes and how much on general clinical governance and management systems. And the idea in their organisation is that they should do both. He believes if you have too much emphasis just on clinical governance and management systems, you do not communicate with the actual workers up there and to achieve improvement you need to do that. So they try to do both, but they have very reliable good clinical data to show that their clinical processes are not well taken care of and that means neither their management systems are in order. And this data actually helps them to realise that, so you get best of all sides.

Klas- so there is no more discussions weather to do it that way?

Einar- we have decided to do it, but there is still a debate. But what they see is that the first team, who has done this way the inspections, are really excited and they see it so useful and they do smth. they haven't succeeded before. They have soon meeting with all the county governances, who do the inspections and hopefully they will stand up and stay that this was very useful and the way it should be.

Anna- Do you plan to extend the inspection method to also another clinical issues beside sepsis? How do you ensure that people don't start to gaming up and only do this sepsis part really good during your regular inspections?

Einar- I suppose CQC refocuses on more narrower things and go more into depth, but it is hard to tell if smth. else will deteriorate due to that. But sepsis is really important and it is the major killer in the hospitals, so they should have this in place. And they think that if you handle sepsis processes good it will help also your other clinical processes, but they cannot be sure of that. They do not know what the next inspection focus is, but they will go and do the other inspections later.

Hanna- what kind an inspection teams you have? You seem to have very much staff.

Einar- typical inspection team will have 4-5 people: clinical expert(doctor, physician) in sepsis management (hired externally), the lawyer, a doctor and the nurse maybe.

Ester- As I understand, you start collecting data in the hospitals while patients are in the hospitals. Would it be good to start collecting data before the patients come to hospitals (read the diagnoses, primary care etc)? Are you looking into that too?

Einar- No, they do not look into that. They discussed that, but it makes it too complicated and too complex. Its already a lot of work to collect the data now, but It's a good idea and they are discussing it, but it would make the inspection too complex.

Ester - would be also interesting to have interviews with patients themselves and if you would like to go further with this process you can find out what beforehand and afterwards were there and why they have been there and what the final results sound.

Einar- yes they could do that.

Lena G- Do you work together with the patient safety programme, because they are working in this area of sepsis?

Einar- yes they are working together and they inform each other. And they were about to do the same programme. They are really keen on them doing this. What the problem in safety programme is in Norway and probably other countries, that it is hard to engage particularly leaders and there are

maybe few eager people at one ward at the hospital, who will initiate to implement the project, but not hospital wide or cross the hospital. And what they see when they are doing the inspection is that they engage the top management and what they think is that they will have a better climate to implement the programme. Unfortunately they are just now changing international standards what should be done against sepsis. There was article in Jama couple of months ago saying that they will change the definition of sepsis and due to that they have to sort of postpone the patent safety programme, but Norwegian inspectorate co-operate with them and by doing this they think they will have an added value.

The Netherlands, Ian Leistikow, , Dutch Health Inspectorate (IGZ)

Will tell where they are now with regulating or investigating what they call "serious adverse events". In the Netherlands there is a law what mandates all health care institutions to report serious adverse events to Healthcare Inspectorate. Those events are those where patient dies or has serious harm due to issues related to quality of care.

Has sent pre-hand an article **"Learning from incidents in healthcare: the journey, not the arrival, matters"** I.Leistikow, S.Mulder, J.Vesseur, P.Robben, 2016;

He will then show the pictures that were not in the article. Shows screenshots of their electronic scoring system. These are the questions: how fast after the serious adverse was discovered that the analysis start? And they can score <2 weeks, >2 weeks or don't know. They use score mechanism what automatically creates a score. Shows how they show separately every sent event analyses. They have approx. 20-30 analyses reports sent every week. They will then score every sent report and discuss them within their team. Each score will be visualised on the graphic overview they will make over every (92) hospitals. Shows examples. There is also timeline showed, so you can track the hospital or each progress over time. As he also explained in the article, you can see the moving average of 5 previous filed reports. They find it interesting as that way they do not only know the status at the moment, but they can also see some form of movement. In current shown hospital case (graph also in article), you can see they are getting better, which means they should have other kind of tone in the letters addressed to this hospital, when at the moment they are getting worse. You can also see the Dutch national average, which has risen from 64%, when they started 2,5 years ago to 78% (80% now actually), so they are getting better. They can also differentiate by the types of hospitals. They can compare small hospitals or big hospitals, as you always get discussions and that way you can compare similar hospitals. So those hospitals, who score too low and report too few adverse events, those are the hospitals they can target and go to them and say that they are either too good, because they do not have any serious adverse events or they have problem with the reporting system within hospital, because they won't get people reporting to the board or the board doesn't find important enough to report to inspectorate.

Klas- How do you handle the other ones? They have hard discussion in Sweden, saying to hospitals "you are very good at reporting serious events", but sometimes they have hit the limit, when they have too many and there is no good way of handling. Do you have sort of limits for those cases?

Ian- Not yet, because at that point there is very much focus on the content. So if they have hospital who reports 20 adverse events from 20 different wards, they have different discussion. Or they have

all cardiology reports, then they ask “what is going on with your cardiology department?”. They spread out the reports.

Lena G- can you tell more about what kind of incidents they are obligated to report and explain more what is this shown score actually shows?

Ian- This score is based on the questions, what are also brought out in the article. Most of them are based on WHO guideline on ‘Concise Incident Analysis’ and supplemented with extra items on patient engagement. Those questions should tell something about learning process of adverse event.

Definition of adverse events are very broad and it’s definition is also in the article (A sentinel event). Very important article recommend to read and what inspired them was published in BMJ (2015), Vincent and Amalberti “Safety in healthcare is a moving target”. It is very significant article for us as regulators. They say in the article that a serious adverse event, like harm, they change over time. What they now perceive as a harm is different as 5 years ago and will be different 5 years from now, what means that it is very difficult to object or compare harm over time. It differs also between people.

Jooske- Is it also true that if you are not too scientifically working, it difference very much?

Ian- Absolutely true. They have lot of discussion in the Netherlands, also in the media, about hospitals not reporting serious events. If you look at the cases what media has set on spotlight as serious adverse events, they often do not fit in the definition what the law says what is serious event or quality of care. And because inspectorate and healthcare professionals perceive it differently, the opinion often difference from what public perceives and conceptualise as quality of care. Thus the difference what should be reported to inspectorate and thus the huge public debate on hospitals hiding things on inspectorate.

Esther- What happens in the Netherlands is that there is a shift on a view on adverse incidences and reporting them, where the context should be law and view of regulatory organisations, to more perspective of the client. The client perspective is becoming more and more important than not just the laws, but also the work they do as inspectorates. Also in media, politics etc.

Ian-not only healthcare, but safety as a whole. Example from healthcare: Few years ago resuscitation, for us was not classified as serious harm if the patient after the resuscitation did not had harm on rest of ability. From the patients perspective to be resuscitated is a serious event, so now we find that resuscitation is a serious harm.

Emily- To what extent regulation might help to change the definition of what a serious event is if the regulation could actually make it safer, the fact that it means the definition of the boundaries are changed?

Ian- The boundaries are definitely changed and they always change, that’s the whole point. What they are now saying in NL is that you have to make a clear definition of what the serious adverse event is, but that’s impossible because the boundaries will always change. His opinion is to extend the public opinion in clear way, that it’s not the definition what is the problem, that it is our

changing perception of safety and acceptance of safety and harm. So we should change with the society. People will be always worried with something.

Hanna- what is this method and questionnaire you use? In Finland they have a big discussion on how to diminish the bureaucracy and they try to get away from separate plans and descriptions and documents. WThey say that the action is the most important. For example you have the aftercare – is the aftercare described and what is described there? In Finland they say it can be described, but when you go and look at it, then you can be sure that it is actually the way it is. And when do you say that the reaction of the board is adequate?

Ian- This is something that also shifts over time. When they started measuring in July 2013, then they saw that >40% of reports (graph shows the shift), there were form of description of the aftercare of health professionals. They think it's important that healthcare professionals who have been involved in serious adverse events should have some form of care as well. Because damaged health professionals deliver bad healthcare. That's why they put that question in and if the hospitals do not describe it, they wrote letter back thanking them for the report, but mentioning that they did not describe the aftercare of the medical professional and asking them to do so in their next report. So basically they are putting things on agenda by asking them. We have seen that it has risen within a year from 40% to 80% and it's going to stay there. Now we have seen that more and more hospitals actually implementing systems for this aftercare. How do we judge it? If there is anything in the report suggesting the form of aftercare, we say 'yes'. And now it's time they start thinking if anything is good enough or they should start going more deep in and start looking the quality of aftercare. In the Netherlands, in the hospitals they have special teams, where the medical staff turns to if there is problems. Therefore they write' yes', but they know from the practice that doctors would never go to this team. It is not the aim to create more bureaucracy, but to put things on the agenda. We are making it norm by showing them their own data.

Riitta- It's a very nice quality improvement tool, because it is some kind a process checking list. You can check if you have these thing in your process or not and if not, you have to add them there.

Ian- Problem we see only is that reports are getting bigger and bigger. The amount of pages in this report, when they started it was 2-6 pages, but now the average is 15-20 p. They feel that they are creating bureaucracy now. They see that it has been useful, but because they are asking so many questions, they are putting so much in those reports, which doesn't make them better. Now they are looking the way to help hospitals to make them smaller again and bring them back to 10 pages as this is enough to describe when smthg went wrong.

Lena G- In Denmark you are not obligated to make those reports for the regulators, but they always mention serious events in patient safety database. They have system, that if the patient dies, who they did not expect to die, they have to call the police and fill it in the database. What they are afraid of, is that the hospitals do not fill in all the serious events as it can give them some problems (self-incrimination).

Ian- A good adverse event report would never be self-incriminating, because it looks at the system failures and not the individual failures. If there is an individual error, neglect or wilful harm of the

patient, then you should not even do the serious event report, you would have to take that individual out of the system and find out how this individual could do this within this system.

Jooske – To explain more difference between the Danish and the Dutch system is that the Danish system is much more punishing. If the people afraid of the punishing they do not feel comfortable to open up.

Ian- Example about the report, where the individual oncologist where given all the blame describing not suitable medicine for the breast cancer patient, because the doctor did not checked the pathology report of this patient. Inspection did not agree with the report saying only that the individual oncologist did not do its work well. If that is really the case the hospital should have looked if this doctor made all the similar mistakes same time with the other patients, but they did not do that. They should have looked in fact how was the system around this individual oncologist shaped. How the doctors previous assessments went, the team around him/her etc. To find out if this individual really was the sole cause of this serious adverse event. They should have looked:

a) What other similar mistakes the doctor made at the same time;
b) System failures why this individual did not do his work on time properly.

Other possibility is that the individual was not countable at all of this system failure, but they should have had multidisciplinary team, that looks in all those oncology patients and should have seen that this patient was getting the wrong medication. They as inspectorate do not accept hospital blaming an individual for a serious adverse event. Even if it is individual fault, it is still also a system failure. From the 1000 of report they assess within a year, maybe 4 will result with individual accountability.

Lena- wants to mention the study they just finished in Sweden, where they looked at 95 reports sent to IVO. They went back to the caregivers to look what happened a year after. They looked at the suggested interventions, interviewed staff to check out what had happened. They find out that 75% of the suggested actions were taken, but what they also saw was that many of those actions were contra-productive. They were not able to improve safety at all, they were not known by the staff. What they suggest in their report is that beside action plan, to also make an implementation plan and to identify obstacles and how to remove those obstacles. That would be good compliment to Dutch study.

Ian- So IVO are addressing 2 issues:

1. Improvement recommendations are not the right recommendations;
2. Improvement recommendations are not implemented.

First issue refers to quality of the adverse event analysis. It's not useful to follow up recommendations which are not good. What they did is to first focus on the quality of the adverse event report. They put their energy to find out if the hospitals are at least capable of producing a proper adverse event analyses leading to proper and useful recommendations. And now they are on phase that they should check the follow up. They visit hospitals yearly to talk with their board. Now they also have unannounced site visit with adverse event report in their hands and look if the recommendations set by board are actually implemented. This is new and this is what they are doing now.

Lena- Would be great to compare the results.

Ian- Yes, absolutely. There are 2 things he likes to discuss more. First do you think this is a proper way to find out what is happening in the hospitals as this is ' a paper', so they are basing their score on paper report? And second- what would be the next step? Indeed creating lot of bureaucracy and perhaps with those hospitals, who are scoring very well throughout year, they should do smth

different with them and stop asking them all those reports. Maybe they should trust them to do it in a quicker linear way and to focus more on improvement of the measures and implementing them and to follow them up?

Showing also graphs about patient involvement- the serious adverse event reports shared with patient or its relatives. It does not have to be physically shared with them, but discussed with them. When they started asking this it was <20% and since they started asking it, it has risen to almost 70%. Even more important question is, weather the patient or its relatives where asked for an input? When the team makes the analyses they talk with the nurses, doctors etc, but they should also talk with the patient/ relatives. This is very difficult for the hospitals to do. They do not want to do it and they find it very frightening, but still since they asked they have started to do that. So they pressure hospitals on patient engagement and this is a major shift in the Netherlands.

Riitta- Can you see it in those reports that they have been talking with the patient (Ian-yes) and can you see the quality of it?

Ian- Difficult question as it depends how you define quality. He is defining quality that they are doing this. Example, when they first started to do this, often the patient called and they had read the report and said that it is not true what is in it. It happens a lot with pre-natal cases (i.e. what time the gynaecologist actually arrived), lot of emotions involved. What they did was that they called to hospitals and asked them to talk with the patients/relatives and let the inspectorate know the outcome of the discussion, because they do not want to be between and having those discussions as an actual regulator. So they try to prevent it by asking the hospitals to engage the patient before and if the patient endorses the report, then the report is good. They could stop the bureaucracy when the patient endorses it, but it's the future. But they see there are less such discussions with inspectorate and if the patient do call, then usually the hospital has not engaged the patient.

Esther- For the lot of patients the whole process is very complicated. What they see in social and youth care is that people with the adverse problems have the least intelligence to know where to go with the complaint and do not understand what doctor are telling them.

Ian- It is little different as they ask hospital to be actively engaged. They do not ask patient to understand all the medical terminology, they ask the assessment team to include the perspective of the patient and that can be however the patient perceived it. But they are seeing new problems rising. Example, if during the assessment of the serious event, you find out that it was actually not a serious event, but complication (nothing to do with quality of care, but with the health condition of the patient), then patients have hard time understanding it. They think that they are covering something up. But they think those issues are fine, that they are part of learning process.

Anna- When the serious event, what could have been prevented, happens in UK, they have regulations (Duty of candour) that everyone who has registered in CQC as a provider, they have legal obligation, when something like this happens, they must tell the patient and involve them. It says you have to do it, but not how and if they do not do it, CQC can close them, fine them and take number of different actions.

Ian- then you will soon face the same problem as they on definition question.

Anna- they have massive discussions. They have 2 definitions- one is for the NHS (reporting to a national reporting system, which is prevenient to this) and one for all their agencies (social care).

Sweden, Klas Öberg, Lena Weilandt, Health and Social Care Inspectorate (IVO);

Klas- In broad perspective it is really what is effective in inspection, how do you make difference in changing the ones we inspect.

-

Short introduction about IVO, the organisation.

Question is when do you think the inspectorate are doing good work? Ian made very good working group discussion when we were in Gothenburg with Don Berwick- are we just creating fear or are we part of the solution changing the healthcare system and social services? They start discussing it 2013 when they were still together with the Social health board if the inspectorate have a right focus. He believes they really made a shift, that they are not about fear and their aim is change and the change is for the high quality of care for the ones we are here for- the patients. As was mentioned before, It' s really the European, global idea that patient is in focus and listening the previous presentations, he thinks that they are little bit behind in Sweden, but still they are changing both the inspectorate and the idea of the health care, the patient involvement. But have to admit that when they are discussing the idea of involving patient within the inspectorate there is still not 100% of people behind it. Now they have discussions within management team how they should really do that.

Lena W- On Slide 5 you can see what they consider to be effective supervision: patient focused, risk based and focused on things that really matters to make a change. And it should be cost-effective. They have written it into their policy.

Klas- They have made actual map, which going from Risk analyses to focus on essential matters. Then they have methods to get the information. Then they have to really give information back to the providers, because if you really want to be effective, you have to give feedback to the ones you inspect and to them to make the changes. Dialogue after the inspection is important.

Lena W- and the tools are based on the effect they are anticipated to have on the supervised entities, so it is really matter of efficient methods. The policy they have is meant to be something they can aim in the long run. They do not have it presently, but this is their aim and vision and they use it on daily bases when planning the inspection and revising the reports to look if this is according to their policy. Right now it is under the implementation. User and patient perspective is not there yet, they have good examples within the organisation, but it is not systematic. Also risk-based supervision and support learning and development. Feedback to those inspected and stakeholders are important part they are discussing right now. Dialogue and also presenting good examples and not only reporting back pour quality. And they are about to Following up the supervision entities opinion on inspection. They do regularly questionnaires.

Klas- If you would make a peer review of the Swedish inspectorate today, you would not find that this is how they work 100%. This is their goal and how to implement this idea. They still working on the fear bases theory a bit.

Lena W- What is new in their policy is that they should follow up the effect of supervision on users and patients. They do not do it right now not at all, maybe some good examples.

Risk-based supervision is something they have clear direction on.

Klas- Here is EPSO really part of their solution. When they started as a new inspectorate, they decided to create national risk analyses and EPSO had a working group, which has been very helpful for them to create their own risk analyses and to learn from very complex system of French to some more easy going ones how to put those risk analyses together. Then they really used that to

focussing on their inspections. 2014 they made an analyses of one of those regions. They put quite a lot of data together. There were 3 problematic areas in this region – acute care, psychiatric care and primary care. Now they have been systematically focussing on those 3 areas and in more deep and following up.

Lena W- this was very appreciative by the region as it was talked there a lot and there were high expectations that they would continue to work this way and keep looking the pointed out risk areas. They still have problems with psychiatric care and they were working together with the regional office, with the management board of the facility, but what happened is that they felt after 2,5 years that they ran out their options. They had made recommendations, made them pay huge fines, but the adverse events kept happening. They have lifted up now to management level and the political and now they see results, which are quite interesting.

Klas- when they did that system analyses 2014, they met with the whole management team of the hospitals and with the responsible politicians to understand if they have the same view on the problem. This was really good meeting and after that they all agreed what the problems are and where to focus on.

Jooske- Did you described those findings? Did you made a report? Maybe it even can be translated as one of the things we discussed in the Risk working group was that more things could be look at the management level and focusing how the management was focusing on risk.

Klas- They have it in their report and it is published in Swedish.

Lena W- When they run out of the options, then the region made their own action plan for how to solve this problem and they supported them by looking at all the actions they suggested and made sure that the high management new about those suggestions and that they were actually followed through. And that is what actually have shift the quality.

Lena G- It is very interesting as they are working with the same thing in Denmark. Didn't' t you had problem pressuring the political system?

Klas- No, not really. That is really different if you look what happened in Denmark, where the press really came after the inspectorate, but in Sweden the press were on the health care and not on inspectorate, so the press have been surprisingly nice to them.

Ian- Can you elaborate more what where the serious events causing the problems?

Klas- suicides in the psychiatric care ward, huge amount.

Lena W- half of the suicides where in connection with the health care at the ward.

Ian- and your suggestions did not helped?

Lena W- They did 6 inspections during short period of time and will continue with that. They are looking their adverse events reports.

Ian- What they need to fix- suicide happening or processes to prevent suicides?

-

Klas- Management. They have changed a little bit in the process, but the results are ending with the suicides.

Ian- So what they have to fix is ending of the suicides?

Lena W- Yes, and not following through their investigations. I.e. they did not follow their recommendations to correct their environment, where there were still things available in the rooms for patients to conduct a suicide.

Ian- And then you scaled it up to a regional level and made them responsible implementing those measures and then those measures did get implemented?

Lena W-By joining the management of the region , they hooked up with them as partners.

Hanna- what do you exactly mean by the management team of the region?

Lena W- Council level, the commissioners. Political level.

Ian- Did you find out why the recommendations were not implemented? And could have there been structural problems related to county level, which had effect why those recommendations were not implemented? For example if you do not get money to change things.

Klas- We had exact same problem with the emergency care and they saw that their recommendations could not be followed, because the one they spoke to did not had the tools, the tools where high up, so that was the lesson for the inspectorate to really address the right level for the right solutions.

Lena W- To find out who owns the problem and who owns the solution. In current case, due to all the bad publicity the things were deteriorating, the management were taken away, the staff fled, enormous staff deficit, so no one was really there to pursue the actions. Media had big influence has no one wanted to work in the hospital with that kind of stigma.

Lena G- she is from the learning department and they have had the same topic and big conference with all the regions and municipalities about the suicide problem in the psychiatric care and it is much more difficult than just to tell the hospitals to make sure their patients cannot hang themselves. It was very interesting conversation with entire country, with the people who they invited and with the people they did not know at all, but who were actually working with this. They have special training how to talk to patient and how to make risk analyses. It is difficult and you cannot regulate them out of these problems, it is completely different setup. She personally thinks it is too simplified to inspectorate to come and tell to do that.

Klas- That is actually one of the new methods they use, after inspecting one or two, they have learning conferences, where they invite people they think are good at this and then they discuss the problem and what they think is the solution (not the inspectorate).

Lena G- It is not always the matter of inspectorate to offer the solutions, but to bring people together to discuss it and find out what can they do about it. It's very complex.

-

Klas- Coming back to risk-based supervision, then they did analyses, but with different focus for 6 different regions and they realised that perhaps it is better to have national theme and national focus. They have 6-7 national focuses this year.

Lena- presents an example from the primary care (slide 9). Hoping to go home with the good ideas for that risk-analyses. Is it a good idea to narrow down and do the pin-pointing? Do they address it the right way?

Next steps to find how to measure and monitor the effects?

Jooske- Do you really want to measure?

Klas- Measuring can be done in many different ways, but it is open and four dimensional so it can end up that they do not measure anything. To just someway get an idea if they mattered.

Emily- Do you have any social researches in your organisation? As in CQC they are trying to find out what impact they have and they are doing surveys with providers they supervise.

Klas- They are doing now interviews with the ones they inspect and if they believe if inspectorate have had any effect.

Einar- Few comments how to measure. They have done surveys and the challenge with surveys is often that you tend to ask small amount of people in the entity and you tend to ask managers and managers are much more satisfied and tend to exaggerate the effect of inspections. They are generally very happy and want to please and say that they have done so many things. And then they go and sit down with the actual workers and they say: "well, they do something up there, but it has no effect at all". That is one thing to think about it and the other thing is what should you take responsibility for. Should you take the responsibility of improving quality and safety? Yes, to certain of extent, that is what we want to do, but you cannot improve it. So your mission is maybe to detect it, make it public and that is when you are effective. If you could improve both, which is of course the best, but you should also look at the measures that measure your work and what your mandate is, because we tend to take too much responsibility and go too far and want to do too much.

Klas- Both agrees and disagrees. Agree that it is good to narrow down the responsibilities, but if we stop there and say that we never have any effect at all on change, then why do we put all those millions on the inspectorates..

Einar – What they try to do in Norway is sort of in-between, to go on with the process measures, because we could see improvement in process measures and to link that with our work. That is a good middle way.

Hanna- In Finland they have new elderly care act from few years ago and it was decision of the parliament to have to have the follow up. Then they did survey together with their health and social care research. It was quite big questionnaire, but it was connecting also questions about supervision and its role. Situation was different as they wanted to put all their efforts together of research and development and regulation to make some changer for the better elderly care. But there are things that depend for a very great part on supervision. For example they took up the question about time between morning and evening meal and at least that as changed within the few years. They did

follow up study/ questionnaire few years later and now they are going to do it for the third time next autumn. The problem is that they cannot tell exactly what the effect of supervision is and what is happening in the society naturally. Do they make the change because they know that you are coming to inspect again?

Klas- That is really the sustainability of the change, that you have ensured change which could be used and then after an half year you are back to basics.

Ian- agrees with Emily to think about having other type of researches involved. Those are like proxy measures and if you have enough different proxy measures, you can triangulate and then you can probably see that you have certain effects. Then its more qualitative research than quantitative.

- **Denmark, Lena Graversen,** Danish Patient Safety Authority (Styrelsen for Patientsikkerhed);

Works with the complaints and patient safety database. Introduces the Danish patient safety database, started 2004. They do not call serious events 'adverse serious events', but 'patient safety incidents'. 'Adverse events' is for the medical products usually. 2011 they emerged also complaints into this database. Reporting is mandatory and they have very broad definition what to report. It is confidential, but they have lot of problems, because police and press is very interested in their data, but they are not allowed to see this data, because it can be self-incriminating for the person who provide them. They can have very aggregated numbers sometimes.

Esther - Does those events happen only in hospitals or also in home care etc.?

Lena G- Everywhere were care takes place.

(will be continiued).

Complemented with the notes from Anna Becket:

Danmark - Danish patient safety database

- Moved to work in complaints department – now it's been brought back into the inspectorate, and now I'm leading the team database
- 7 people in unit, 80 in the inspectorate
- Hospitals say we're too small so they pay more attention to the press
- 2004 the inspectorate collected patient safety incidents, in 2011 moved it with complaints instead. Reporting is mandatory and with a broad definition – reporting is confidential
- Have 5 regions, 90+ municipalities
- Have case handlers so that the staff member/member of the public reporting an incident remains anonymous to the regulator – case handler also decides if RCA is required – most are nurses and are employed by the health organisations
- Complex as cases handled at different levels – primary handled at municipal, public hospital and independent GP at regional, private hospital in house

-

- Public mostly use complaints rather than patient safety (175k complaints, just 2k from public)
- Incidents are mostly medicines, falls,
- Have lots of identical incidents (e.g. not giving meds at right time in nursing home) – plan to start aggregating these
- New plan is to involve staff better, might reduce burden although pilot suggests not by much
- Means have better local overview, much easier to report incidents (as now a simple line in a spreadsheet),
- Now inspectorate brings together lots of data (complaints, alerts, press) , looks at whether to inspect, or learn or something else… , regions can also run quality programmes

NL YOUTH inspectorate (a co-operation project of 5 inspectorates in the Netherlands : Youth / Health and Social Care/ Income and Tax/ Safety and Security- Justice/ Education)

- We investigate most serious events – mostly when children die when living with their parents

- 5 inspectorates work together (income, safety, education etc) as most families will have had sustained help from all of them
- Think about how well they all worked together (we know the child is dead so can't have gone well)
- 2 important issues in NL which make investigation more complex – 1. Children and adults don't get institutionalised, they get help at home, 2. In 2015 we had new laws to decentralise responsibility for youth and social care, laws about income and debt help etc
- Now some of orgs are under local, not national supervision which makes it more complex (but local arrangements not all in place as it's too soon)
- Start with local gov – talk to mayor responsible for youth/health care. Tell them we will investigate. Ask them which orgs were involved (sometimes know, sometimes not). Try to keep them in our process and are interested in our published reports (as are media etc)
    - Have about 15 cases per year, seeing this increase but as decentralised we don't know why yet
- Changes are making it hard for local professionals to know each other and how to contact etc – very fragile
- Look at all the files, interview the professionals (20-25 professionals), and families if not dealing with criminal issue
- Have learning conferences to share the whole picture, bring together everyone, ask them to discuss what improvements they would like to make
    - Then do a shorter version with the senior management, and bring the recommendations from the practitioners for them to discuss. Mayor is involved in this so that they (local gov) can take it forward.
    - We monitor twice a year, and check in every couple of months
- Did 5 of these in the year
- I have 30 inspectors for all our work which includes normally programmed investigations. Now trying to start working with local inspectorates but hard if they aren't there/established

– their quality is currently not high enough in our view so now we are inviting them to come to work with us / shadow us so they upskill
- Our reports are always published so we have a comms strategy on what we answer and when etc – also talk about it with local gov as can be very effected by it too (work with their comms teams)
- Also do an annual report with biggest learning points from the year which brings out common themes, and also arrange a national conference on this for local government and the relevant organisations, to try to develop strategy/vision for networks – found big gap between what professionals do, and what politicians think they should do (e.g. on person-centred care, as public don't always know what they should ask for)
- Looking to find a leaner, smarter way of working – but getting asked to investigate more – we use criteria to decide when to go/don't go
- Some are now arranging local meetings to discuss a few potentially serious cases to ensure they have thought about the gaps
- Seeing increase in voluntary help – not necessarily regulated so following the story is becoming more diffused. Means our mandate is being stretched.

England, CQC

- Finland is looking at value – but want to look at bigger picture – want to look at outcomes/effects
- We want to know what licencing process costs as need to charge a fee – productivity is the focus
- Can do lots of inspections, but if inspect the wrong things then it's not a good performance – trying to find the measures
- Check BMJ article saying our work doesn't correlate with outcome measures
- NL – found we reduced avoidable mortality by 50%, same day a GP in north killed a patient, so the public wasn't interested in the 50% story.

Finland, Valvira

- Discussion about leadership
- We can measure processes but not always the impact on patients
- 5 hospital districts with universities, 21 others
- Psych unit used to be one of the best – led to complacency in small, isolated unit
- In 2012 concerns were raised – media, director of health care district, and chief physician (who was new in post)
- Got new leadership, new methods, started working closer with the university hospital. Renewed all processes, co-operated more with health authorities, increased education
- Problem – staff felt we thought they were the villains so wanted to leave – our challenge was ensuring they felt supported and worked with us
- Vital that supervisory org supports a new leader, especially when they make unpopular decisions

-

- Moving to self-monitoring but don't have national dataset to support this
- Now ministry of finance asking how can improve the efficiency/effectiveness of healthcare supervision
- Healthcare will be privatised at the same time – this will be a change as before we didn't regulate the municipal provision

Discussion about the cases and the proposed solutions.