European Partnership for Supervisory Organisations in Health Services and Social Care

Meeting Report

EPSO Working group Effectiveness – Copenhagen, Denmark, 16th April 2018

09:00-12:00 at the DPSA (The Danish Patient Safety Authority) offices

Report made by Mari Murel, EPSO

Participants:

1. Anna Edwards, CQC, England (chair)
2. Victoria Howes, CQC, England
3. Ardita Baraku, Kosovo
4. Leifur Bárðarson, Iceland
5. Peder Carlsson, Sweden
6. Indra Dreika, Latvia
7. Muhammet Serdar Erbaş, Turkey
8. Tove Gemzell, Sweden
9. Alexandrina Gigova, Bulgaria
10. Nina Jagd Andersen, DPSA, Denmark
11. Dan Jesper Jensen, NBSS, Denmark
12. Ali Kolpay, Turkey
13. Alvaro Moreira da Silva, Portugal
14. Advije Mala, Kosovo
15. Anette Lykke Petri, DPSA, Denmark
16. Eve Pilt, Estonia (will arrive little late)
17. Atanas Sarandev, Bulgaria
18. Anette Sejer-Perthou, NBSS, Denmark
19. Andrew Terris, IFIC, New Zealand
20. Jooske Vos, EPSO
21. Mari Murel, EPSO

- **Introduction and updates by Mari Murel, EPSO**

EPSO has convened four prior meetings for the Working Group Effectiveness. At the last meeting , September 2017 in Reykjavik, we tested several risk problem cases on a theoretical framework that we have been working on to use it to discuss how to formulate goals of regulation[1] and make the effects of regulatory actions visible.

[1] The terms regulation, inspection and supervision are sometimes used interchangeably. For clarity we only use the term "regulation", and with this we mean: "sustained and focused control exercised by a public agency over activities which are valued by a community" (Selznick 1985)

Please see meeting reports from our previous meetings here:

http://www.epsonet.eu/effectiveness.html

(Username: EPSOEFFECTIVENESS pw: epsoeffectiveness)

Previous chair of this working group Riitta Aejmelaeus (Finland) has changed her position and doesn't work anymore in the area of health supervision. As the Netherlands is not participating in EPSO network this year, Ian Leistikow was unable to participate.

He did asked us to share his recent research and promotion work *"The proof of the pudding The value of governmental regulation of healthcare quality and safety".* You can find it at our website: http://www.epsonet.eu/related-research-2.html

We have a new chair from England- Anna Edwards from CQC, who is introducing her current project focusing on patient safety.

- **Anna Edwards, chair of the working group introduces the new topic:**

Although CQC is regulator in both health and social care this current project is focusing in just health care (for now). Maybe some of the learning from it will tip over to social care, but for now the scope is just focusing on NHS Hospital trusts.

Anna Edwards presentation available at EPSO website:
http://www.epsonet.eu/effectiveness.html)

Purpose: The Secretary of State has asked CQC, in collaboration with NHS Improvement, to examine the underlying issues in English organisations that contribute to the occurrence of Never Events and thereafter the learning we can apply to wider safety issues.
Outcome: A report into how organisations can reduce the risk of Never Events by promoting the positive work identified. Identify how compliance with mandatory safety guidance can be increased. Understand the learning which can be applied to other safety incidents beyond Never Events.
Timescale: Report in October 2018.

There are expectations that if trust follow guidance then we can stop the never events happening altogether. It should never happen and we can put things in place to ensure that it never happens. There are lot of safety incidents that happen and they collect that data as well, but those are incidents they accept that happen and that they cannot stop them, only reduce them. In case of never events there is a goal that they can stop them altogether. She is not sure it is achievable as long as there is a human factor- people treating people.

Example of a never event- wrong side surgery, tube placed wrongly etc.
Official **definition**: *Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. The occurrence of a Never Event is likely to be symptomatic of underlying system weaknesses in an organisation.*

Never events in England get lot of attention and it goes to top on the political scale. That doesn't encourage trusts (providers) to report them and up to January 2018 they even get

fined. They do have obligatory to report all kind of safety incidents (central system for that) including near misses and simple things like falls. Currently 1,8 million incidents per year, but never events get a special flag and CQC will be told and Improvement agency, Commissioners, Secretary of State etc.
This does not encourage to report all incidents, like near misses. They might not be reported at all or downgraded to serious incidents.
Last year (2017) they got 6.400 serious incidents reported and among them incidents lead to death nearly 4.600 cases. They do not necessary make difference between avoidable and not avoidable incidents. For proportionality- they cover 53 million people per year

- **Examples from other countries**:

Denmark-
NBSS: In social services they do not have the reporting system.
DPSA: It is mandatory for the health services to report all adverse events.. They do not have category of 'never events' as they do not think they can eradicate them. They have category from 'no harm' to 'mild harm', 'moderate harm', 'serious harm' and 'death'. Serious and deadly events will be analyzed at a national level and all events are analyzed locally to learn how to prevent them to happen. DPSA cannot access or see by who it happened, they are more interested to find the patterns and tendencies what result on serious incidents and death. They have separated offices who handles/analyses (Knowledge and Learning office) and who supervise (Supervision and Guidance). The analysts have access to reports and the supervisory office are not allowed to look at the reports or get any information from that office, to avoid punish the providers for their failures. There cannot be any sanctions (neither national or local level) based on reports. The source for sanctions have to come from other way (complaints, patient claims for damages etc.). The purpose for those reports is purely learning. They give feedback to local risk manager in the health care organization if they see a pattern or tendency. It is difficult to use it as a strategical tool. The reports are very descriptive, very qualitative. They receive approx. 180.000 reports annually. Approx. 80.000 reports come from hospitals.
When an adverse event is reported, the local organisation has an obligation to analyse the event and consider local measures to prevent future incidents. Root cause analysis is one possible method to apply, but other methods can be used. Once a local report is finalised, all identifiers of involved persons, institutions etc. are removed and the report is transferred to the central database where all reports are included in aggregated analyses. Furthermore, all serious and deadly events as well as moderate medication related events are analysed individually at a central level as part of the DPSA's analysis of high risk areas

Sweden:
2 systems since 1996 for social and health care. Lex Maria- legislation that regulates how to report. Lex Sara- same for social care. Started with serious incidents, which caused death and where police didn't felt competency to investigate. Nowadays the inspectorate does not do investigation themselves, they just look what kind of investigations the health care provider has done. Providers are now responsible of the investigations and to find out what went wrong. Sometimes they demand them to do better. Approx. With 50% of reports they are not pleased with. 176 Lex Maria reports in 2017 in Peder (Carlsson, Örebro unit) 8 of them he was not pleased with. 85% the providers were not sure what to do. Their correction is- we are going to talk about it- but they are actually not doing

anything. That cannot be only correction, they have to do more about it (education, change etc.). IVO (the Swedish Health and Social Care Inspectorate) tries to find out the lines how to make the improvement happen. They started to pay more attention to it when the national statistics came that there were 3000 deaths among 100 000 serious events. Now they get approx. 2700 reports per year (2017) and that is not even up to 3000 death events, so it is very underreported. The idea is to reflect and help the providers to see the problems. They are moving away from blame & shame culture and try to talk more about quality systems and how to work and learn.
2 issues:
-quality of investigation what has happened;
-reporting.
There is no obligation to report everything, they just report what providers think they should report. They report the incidents that caused or could have caused serious harm, what could have been avoidable.

Portugal:

Similar system to England, which spends lot of time and tax payers money. This only covers hospitals. Never event for them is a process- from the beginning of the small mistake made in the start of treatment till the worst case end- death. Separately they are not never events. They are moving from outcomes to (incidence) process. They ask people to report and explain themselves, what they think can be done. They move from the patient safety to quality. That they would say- I have done something wrong and now I want to do something better.
They try to process patient complaints together with the incidents reports and every 6th months they do 'top 10' facilities in each region. Those events have close relation to behavior. If the local provider had a culture of quality, it is quite easy to address the question. And then there is administration – they do not want to have never events. They are just acting for the media and politics.
And then there is blame given forward nurse to physician up to the end -Health minister.
Good safety and improvement culture is important- how to achieve that?
In Portugal they publish every year the best ones- the top 10 (outcome). Positive discrimination instead of pointing the finger to bad ones. Confidence in health providers is essential for public.
Protocols are obligatory to follow, pathways are initiatives from outside to follow (pathways to stroke, sepsis, trauma etc.) .
Quality is multidimensional- for some it is clean facility, for someone it is good outcomes, for patient the other outcome is perhaps having no pain.
Protocols, pathways and guidelines will never be the triggers of change.

New Zealand:

Little bit similar to Denmark.
They have separate Health and Safety Commission body and it solely operates under the quality and improvement and links, but no authority to sanction. The Health and Disability Commissioner has right to sanction. They have also additional authority– the Accident Compensation Corporation, who cover claims for treatment injury and who publish treatment injury case studies.

There is a severity assessment rating based on outcome and corresponding code from SAC4 (Minor/minimal) to SAC1 (Severe). *ref www.hqsc.govt.nz/our-programmes/adverseevents/publications-and-resources/publication/2937). NZ uses the WHO taxonomy of classifications for patient safety. There is no distinction between preventable and non.

So they are making the analyses to see if there is a clustering of serious events and then they do a quality report. There is also something called 'the open book'. All the providers are encouraged to keep an open book with reports about the case studies- what they have learned from and what they have done for. The statistic shows that there is an positive effect after the providers have started using the open book.
Every year the Health and Safety Commission produces the reports what about quality and they pick the top themes and show the learning of those and organise workshops etc.
https://www.hqsc.govt.nz/our-programmes/adverse-events/
Its only hospitals for now. They cannot do any judgment.

Turkey

The quality culture is very important in Turkey, the priority for all health organisations. Therefore in all hospitals (both private and governmental) special quality units were formed. Reporting is obligatory because of quality standards (regulative and legislational). Without reporting they cannot make analyses. Key questions are: who will report and what the report have to include?
What concerns avoidable deaths, then for example the mother and baby death rates diminished remarkably after forming those quality units and because of quality implementations. The central governmental health accreditation agency was formed in Turkey and they perform accreditations in the Turkish hospitals. There is special central management office to coordinate all the hospitals quality units and they are taking the statistics from the governmental hospitals about the serious (never) events. And if those cases need further investigation they are forwarded to the department of inspection unit. Key question is also is it sanction free reporting or not. How the sanctions could be implemented after reporting? Doctors and nurses may not be very eager to report due to fear of prosecutions or disciplinary actions.
In hospitals the quality and patient safety (rights) units are separate units. Patients go with their complaints to patient safety unit, the other unit (quality) receives mostly 'whistleblowers' reports.
It is very vital to understand the situations- what is the problem? How can we solve the problem? They need to analyse it. They have information and they can trace back who and were has caused the serious incident.

Iceland

Their incident reporting system is more or less about hospitals or hospital- there is one big hospital in the country. They have had electronic reporting system for 15 years and everybody more or less knows what they have to report. They have almost stopped picking up people who don't, they have enough reports. They only sanction those who won't report, but they rarely do it nowadays. The head of health inspectorate receives all the incident reports, so the inspectors can see them, but usually they do not. They classify them: Mild- intermediate – serious. The serious ones have to be reported separately to the director and those they look at. If they hear about institution that does not perform well,

they can go into the database and see what happened there, but it's not a regular case. They have enough incidents reported, which they can correct and go in and look at them. The Primary care is very under reported. Literature indicates that the incidents are very underreported all over the world and maybe they have to accept it or maybe they have to do something about it. Icelandic experience says that the institutions who are reporting know themselves what is wrong.

Most of countries have under reporting, but we say –we have enough to improve the health care. We keep coming back to questions- what is the aim of reporting? What is the expectation?

In **England** the expectation is perhaps too great – from all the never events to zero events in certain timeframe. Political conflict of interest comes in too.
In their conversation during big workshop they talked with other industries (military, aviation, helicopters, oil, gas etc.) they said lot about marginal gains and accepting that we can improve a bit next year and year after, but we can't improve from one edge to other overnight.
Iceland seems is in that state, where they accept that and do not use their efforts and people to get more and more reporting, but to improve and support those who already know what is wrong. Because Iceland is a small country it is easier to get that culture, in England it is hard to scale it up.

Bulgaria

There is no such system in Bulgaria.
They use their patient complaint system (approx. 700 per year), but there is no dividing them from mild to severe, but perhaps in the future.
Biggest challenge is to change the culture. At the moment nobody wants to report, because of the blame and shame culture. They try to start changing it, starting with few hospitals.

Kosovo

There is no such system in Kosovo.
To find out the patient outcomes you have to be able to follow the patient throughout your system, which they do not have. They do not have health insurance and their health information system does not function well, so they never know the patient outcomes, which is gives them more reason to do something about the quality.
They do have division of quality by the Ministry of Health and every health institution should have one quality coordinator. Public institutions do have them, but she is not sure they know their job. They just started with official job description for quality coordinators (they have had the position 7 years). It is an growing office and there still needs lot do be done in that area.
What concerns incident reporting, they do not have standard procedures or clinical guidelines, pathways or protocols. Therefore it is difficult for inspectors to go and follow if everything was done correctly with the patient. It is also difficult for doctor to know or to defend the action on specific patient.
According to legislation it is obligatory to report the deaths, regardless of the cause.
There is a system for reporting deaths and hospital infections.

And they are underreported and not done properly.
Culture is that people work a lot, but they do not write down what they do and that can fire back. It is very important that in the incident reporting system everything is written down properly, even prior to the incident.

Discussions

Alvaro, Portugal- recommends to start with implementing registration culture (like in aviation)in all levels, because we do not know where the holes are aligning (where it went wrong, where are the firewalls that make difference) and then safety culture.
Instead of ranking, do rating- higher or lower than average.
Promote incentives. Listen public and listen patients.
Goal orientated outcome instead of just safety culture. Safety is often feeling based. Usually you go to hospital and you feel that it has safety culture.

Mr Erbas, Turkey- strategic planning process is very important and beside that performance and prizing-rating system are important. We need to measure health care providers quality to be successful. Therefore they have in Turkey nearly 15 years performance appraisal system. They try to measure and rate the performance. For that they are making questionnaires together with patients, health care providers and managers and using methods like '360 degree method' for appraisal system. It has shown great effect on improvement of performance.

In England they use also ratings and in every year they get better and better in looking and using those ratings to help encourage improvement.

In **England,** it is easy to think that country like that has all reporting system in order, but it is often not the case. They get feedback from the clinicians that there is so much reporting that they cannot see the wood for the trees. They do not know what to prioritize. And if you tell hospitals what they need to prioritize, then everything else gets left and forgotten, even if that is also quite important.

It is important that people know what is going to happen with those reports and what for they are used (punishment, learning etc).

In **England** they get feedback that people spend average 1,5 h to fill in the reports and they do not know what happens with those reports. Supervisors do not have time to read all those reports, because there is so many of them and the questions is if you are going to learn something new after reading 50th one, never alone 60 000 one. So the question is indeed what is the point of all this reporting, does it add up to anything?

Suggestion to add in the future to those reports remark, what is going to happen with those reports or who they can contact if they have questions about it.

Important is to change the language, the mindset – if you start talking about improving quality instead of what went wrong.

System partners. Who is involved in local level reporting to support the hospital? Does hospital does it alone or are there other bodies which support them.

Denmark – there is hospitals and also governmental body supporting them. They have 5 regions and there is also risk manager on regional level supporting them. So there are 3 levels : local risk managers, regional and also national.

In **England** it is quite complex system who are involved, who have a role in patient safety. So for Trust it is quite difficult to know where to go when they need support, when one of those incidents happen.

What lessons can we 'actually' learn from other industries?

There are lot we can learn from the other industries and literature we can read.
Recommendation of great book by Matthew Syed *"Black Box Thinking: Why Some People Never Learn from Their Mistakes - But Some Do."*
It's all about safety culture and how far all the industries have come and how health care is still little bit behind.

Denmark had good dialogue with pharmaceutical industries about packages (look too similar, easy to make mistakes etc.).

England similar with safety boxes that vary within hospitals- they all oblige but they all look different and work different, which is confusing for patient.

Protocols are often too long and not 'digestible' (NICE more than 70 pages)
And there are so many of them- how do you find your way? There is a balance somewhere.

Susan Bennett (Oxford University) has done 3 reports about 20 never events and root cause analyses. It really picks up where people are going constantly wrong on time again.

<u>Culture</u>

How do we promote the culture within the hospital, where people feel that it is the right thing to do, rather than that they know that it is right thing to do, but I do not have time or that it is right thing to do, but no one else is doing that, so why should I.
Do we just have to wait? As it takes years to change the culture or we have to wait till the people who still think that way to retire to be able move on..? Is it about training? Is it about patient education?

In **England** they are picking up that it is not all right how they train their medical staff and there is more they can do and they can make patient safety more prominent within that training. Maybe to make the patient safety as a discipline itself as at the moment it is not, but in other industries, safety is a discipline (like fire safety). They know that leadership is important and that the leaders need to promote the safety in a way that it is important. They know systems and investing into systems that support people are important. Politically those systems cause a lot of money. Now all the reports go kind an into black hole and it is hard to get back anything or trace back and see how others are dealing with similar problems or other issues. But world is changing and social media has more and more influence and there are enablers to help to move on with our work too.
They talk a lot about no blame and just culture and how to meet people's expectations when something goes wrong. It is not only educating the stuff, but also public to have

right culture, when something goes wrong. And politically it is difficult as they want to show that something has done about it and someone to blame even if they talk about just culture.

Leifur (Iceland) sees that the problem is that we represent the institution that doesn't speak the same language as the people on the work floor. He comes himself from that work floor and knows that the health care workers think that as they are saving people every day, the safety is part of their work, not something extra to learn. He agrees that it is a good idea that before the health care worker starts the course, he/she should take first a course on safety (only about safety). They do not read afterwards all the protocols, so it have to come from themselves at the beginning. When they get the safety course at the end, they are already too ' indoctrinated' – they are doctors- they know all about saving lives. Therefore it is fundamental to educate them about patient safety at the beginning.

Anna (CQC)- And this safety training is only available to doctors. They have discussions that patient safety training should be available to all the hospital staff, including cleaners, porters etc.

In Iceland they have it ongoing and to all, but there is always some reasons that doctors cannot come to participate.

Jooske (EPSO)- if you make a training and want doctors to come, do not make it to everyone, make special meeting for doctors and you might find them coming. If you make it to everyone, the doctors won't come.

Vicky (CQC)- but question is if we want such a culture to go on?

Alvaro- You have to upgrade the value of the patient safety course. In his hospital the doctors have to participate in 65% of the courses within a year. The patient safety course is their last choice, because it is not about clinical practice.

Tove (IVO) same type of skills what you need for patient safety, you also need for quality improvement. You need to look carefully also what we as inspectors look at, because what we look at has a huge influence into the systems. If we only look at the protocols then there are hundreds of protocols. If we look more from the point of patient needs, they will be more focused on that.

Leifur- We should not look the quality and safety separately- it's a part of entity, integrated part.

Mr Erbas (Tyrkey) Also the safety of health care provider is a key element, because they are very related to each other (example- radiation, infection security). In Turkey a doctor or nurse will take extra responsibility, gets training and gets additional payment. This can be a motivator. Of course the culture remains the most prominent factor. They have to implement control systems into hole system. Education programs are important and as they have central system for universities they can implement special training programs into their education program.

Nina (DPSS) you can start with simple things like they try to have same color coding for the pharmaceuticals and try to have dialog with pharma companies to change their package design, to be more safe and to avoid mistakes made due to similar packages.
She is documenting that case and will write a report about it, which she can share.
She lets EPSO know when it is ready and then it will be share at EPSO website.

Actions

Continue our work. Questions: what did we learned and where do we want to go deeper, more in detail?

Annette (DPSA) – would like to get some research what CQC is using about that topic.

CQC will complete their fieldwork and get some evidence and share some themes and recommendations.

Peder (IVO) – He sees that the institutions have short memory and they changing their heads often etc. How to be part of the developing culture that will last over longer time? How to have lasting impact on culture? How to perform inspection right way to make that impact?

EPSO will make a report to give feedback to CQC based on discussions.

Next working group will take place in October (Sofia, Bulgaria).