

CPL response to the GPhC consultation on pharmacy regulation

09.08.2018

1. Do you think the three types of inspection (routine, themed and intelligence-led) will:

1. Provide more assurance that pharmacies are meeting our standards? **No**
2. Enable us to be more agile and responsive to risks or changes in pharmacy or healthcare? **Yes**
3. Help to drive improvements through identifying and sharing good practice? **Don't know**

Free type comments

Inspection is clearly one way to provide assurance of safe practice and operation, delivering the standards required of pharmacy to provide great care to the population. The assurance being given from a source external of the immediate pharmacy team. To this end we totally support the Inspection of pharmacy premises, the comments made here and below are in the spirit of making these the best possible, and fit for purpose.

Section 1.12 does not lay out how you will drive improvements through the identification of and sharing of good practice; nor is it clear how common misunderstandings can be highlighted & therefore the learnings shared with others in a timely fashion; it simply states an ambition. Hence the answer to Q3 is don't know

Do you have any other comments about the types of inspection?

The consultation does not make it clear how the Inspections can add anything more than the existing model

2. Unannounced inspections: answer in the form of Yes, No, Don't know

Do you think that moving from announced to unannounced inspections as a general rule will provide more assurance that pharmacies are meeting our standards every day? **No**

We have identified instances when it may not be possible to have an unannounced inspection. Are there any other instances we need to consider? **Don't know**

Do you have any other comments on us carrying out unannounced inspections as a general rule?

Unannounced visits will give the public more assurance; however an unannounced visit puts the whole pharmacy team under immense pressure, when they are focussing on patients & patient safety. The immediate impact of an Inspection on the people in the pharmacy is not being recognised, and the impact on the team once the Inspector has left is not being acknowledged, and the impact this stress can have on actions and decision making.

We are aware that bodies like the CQC give Healthcare providers in primary & secondary care notice of inspections (although they do have a caveat they can be unannounced - in the main they are announced). In terms of Ofsted they give Head Teachers of schools half a working days' notice and further education and skills providers two days' notice (though Ofsted has the power to inspect without notice where they concerns).

So totally unannounced inspections as a norm (where there are no known concerns) are outside of mainstream national approaches to inspection. It is reasonable (and with a view to patient safety of the Inspectors presence of disrupting the pharmacy routine, just like any other visitor to the pharmacy) to give the Responsible Pharmacists some notice of this inevitable disruption to pharmacy work flow & operations.

Do you have any other comments on us carrying out unannounced inspections as a general rule?

See above

3. Changes to the outcomes of an inspection

We propose having two possible overall outcomes from an inspection - 'standards met' and 'standards not all met'. Do you think this will make it clear to patients, the public and pharmacy owners that a pharmacy has met, or not met, the standards? **Yes**

Explain reply

With only two options pass or fail - it is clear

We propose having four possible findings for each of the principles - 'standards not all met', 'standards met', 'good practice' and 'excellent practice'. Do you think this will: *

1. Provide owners, their teams and the GPhC with a way of measuring performance? **Don't know**
2. Continue to drive improvement? **No**

Room to free type comments

Any categories, no matter how many may provide a measurement framework, it is their effectiveness that is important. The document is very unclear in how these measures will drive improvement, and does not demonstrate how good practice can be shared if there are simply two categories. Also, what constitutes good practice and excellent practice are definitions that are both subjective from an individual inspector perspective and from an industry perspective therefore definition of such is open to interpretation.

Patients have told us that a pharmacy should meet all the standards to receive a 'standards met' outcome. This means that not meeting one standard would result in the pharmacy receiving an overall outcome of 'standards not all met'. Do you think that not meeting one standard should result in the pharmacy receiving an overall outcome of 'standards not all met'? Answer in the form of No

This pass or fail approach is too black and white. Where there are minor adjustments needed, we would suggest this can cause undue fear with patients and also cause reputational damage, particularly if quoted as a singular indicator regarding a pharmacy.

Note the CQC & Ofsted have 4 ratings – Outstanding, Good, Requires Improvements and Inadequate, and within these there are degrees of actions that may still be required, why is the GPhC moving away from national regulators' approaches? It is inconsistent to a national approach of recognised inspections, therefore not comparable.

Do you have any comments about the proposed wording of the overall outcome of an inspection, that is 'standards met' or 'standards not all met'? Free type answer

This pass or fail approach is too black and white. Where there are minor adjustments needed, we would suggest this can cause undue fear with patients. Note the CQC & Ofsted have 4 ratings – Outstanding, Good, Requires Improvements and Inadequate, why is the GPhC moving away from national regulators approaches? It is inconsistent to a national approach of recognised inspections, therefore not comparable. Standard met and standards not all met are statements that can have consequences for the pharmacy depending on how people chose to interpret these statements. The aim to publish all improvement action plans will help in some way to help people understand the findings, however will they read it, & do they understand the context?

Do you have any other comments on the changes we are proposing to the outcomes of an inspection? Free type answer

For “not all met” is there is no way of knowing externally where there is something that can be quickly put right through to situations where enforcement actions are being taken. Can there be a short period of grace to correct areas where minor improvements are required, and the pharmacy revisited, prior to final assessment, especially if the visit was unannounced?

How is this decision made in respect of the different types of inspection e.g. routine, themed and intelligence-led? Also, the inspector may not observe the practice or view the governance arrangements at a particular pharmacy during an inspection but these may all be present, there does not appear to be a provision to provide evidence after the inspection to demonstrate the fact that all standards are being met i.e. a grace period for the pharmacy to respond. It is inevitable in some cases that all the evidence may not be identified during an inspection. The current format allows for this eventuality, giving a clearer insight into the actual day to day running of the pharmacy. Again this document is not making any allowance for the impact that such a visit has on the pharmacy team & how this can influence their behaviour.

We reiterate the CQC & Ofsted have 4 ratings – Outstanding, Good, Requires Improvements and Inadequate, why is the GPhC moving away from national regulators approaches – it is inconsistent to a national approach of recognised inspections, therefore one could argue not comparable

4. Do you think we should publish inspection reports? No

Explain why

The Inspection reports as described in the consultation are very top line in what they say. Publishing the report as described, with the proposed outcomes will not create transparency as the outcome without the detail, e.g. grading of elements met or not met, will have the significant potential to cause confusion or misinterpretation, to patients and the public. Therefore, rather than creating transparency there is the significant risk of creating the converse. The challenge of having only two outcomes of pass or fail.

Do you think publishing inspection reports will

1. Provide greater transparency about the outcome of an inspection? **No**
2. Provide assurance to users of pharmacy services that pharmacies have met the standards? **No**
3. Enable the pharmacy sector as a whole to use the information in the reports to improve? **No**

No recognition is given here that the existing Inspection reports are already taken very seriously by Pharmacy Teams & top level management, any action plans being made priority. CPPQs can be /are used to help patient's gauge quality of services delivered.

The Inspection reports as described in the consultation are very top line in what they say. Publishing the report itself with the proposed outcomes will not create transparency as the outcome without the detail, e.g. grading of elements met or not met, will have the significant potential to cause confusion or misinterpretation, to patients and the public. Therefore, rather than creating transparency there is the significant risk of creating the converse. The challenge of having only two outcomes of pass or fail.

In terms of enabling the pharmacy sector to use the reports to improve the reports as they stand will only highlight trends in terms of 5 principles.

Do you have any suggestions about the intended format and content of the summary and detailed inspection reports?

Whatever format is used, it needs to be clear, concise, easy to follow and written in such a way it is easy for everyone to understand

Do you think we should publish improvement action plans? No

Will depend on the outcomes and the factors behind those outcomes; again the context is missing. Employers also have a responsibility to their staff. All Pharmacies are relatively small units & this this type of report could highlight individuals into the public domain due to the small numbers of people involved

Do you think pharmacy owners should be expected to display the inspection outcome in the pharmacy? No

Is the question that the met or not met is displayed in the pharmacy? We wholly disagree with this based on the answers to other questions.

5. The website and knowledge hub

Do you think the interactive website and knowledge hub will: answer to each

1. Make information easily accessible? **Don't know**
2. Encourage the sharing of knowledge within the pharmacy sector? **Don't know**
3. Enable learning from examples of standards not being met, and of good and excellent practice? **Don't know**
4. Drive improvements within pharmacy? **Don't know**

The hub may make information easily accessible, only because it is published – it is up to others to read it, and will be influence by how the data is presented, analysed & learning are presented e.g. FAQs that provide the context, causality and solutions, it would not work if it relied on people trawling through the reports themselves, and would need to be anonymised to protect confidentiality. The impact this information would have will required significant uptake to make a real difference, we are unclear if that is the medium to achieve this; suggest it would need to be a multi-channel sharing of learning

6. Publishing inspection reports

Do you have any comments about the publication process?

Rather vague in the frequency of publication, although you say weekly or monthly this does not stipulate the prioritisation of inspection to publication. In terms of a pharmacy with a minor standard not met, then a month may be a long time & it could have been corrected before the report is written in the first instance.

7. Impact of the proposals

What kind of impact do you think the proposals will have on people using pharmacy services?

- Positive impact
- Negative impact
- Both positive and negative impact Y
- No impact
- Don't know

Free type reasons behind your answer

For standards met it will provide reassurance, for not met (and how this is described there will be no opportunity to correct whatever is wrong), if a single minor issue then it may cause unnecessary fear, alarm and loss of faith in the pharmacist & their team with the patients; if it requires enforcement then is the action taken by the GPhC enough at the time of inspection?

What kind of impact do you think the proposals will have on the owners of registered pharmacies?

- Positive impact
- Negative impact
- Both positive and negative impact Y
- No impact
- Don't know

Unannounced visits will have a negative impact for the reasons stated above.

What kind of impact do you think the proposals will have on the pharmacy team?

- Positive impact
- Negative impact
- Both positive and negative impact Y
- No impact
- Don't know

Unannounced visits will have a negative impact for the reasons stated above.

Do you think anything in the proposed changes would have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?

Don't know:

Lack of clarity in the consultation means we are unable to understand the impact these proposals may have on individuals or groups who share any of the protected characteristics listed



Do you think there will be any other impact of our proposals which you have not already mentioned?

Inspection is clearly one way to provide assurance of safe practice and operation, delivering the standards required of pharmacy to provide great care to the population. The assurance being given from a source external of the immediate pharmacy team. To this end we totally support the Inspection of pharmacy premises, the comments made here and below are in the spirit of making these the best possible, and fit for purpose.

Note the CQC & Ofsted have 4 ratings – Outstanding, Good, Requires Improvements and Inadequate, why is the GPhC moving away from national regulators approaches – it is inconsistent to a national approach of recognised inspections, therefore it is not comparable