Update on developing our new approach to inspection

March 2013

Re-cap from last time



- Vision
- The plan
- Proportionate regulation
- Inspection decision framework
- Relationship management
- Our development approach

Inspection Cycle

Registration of new premises Risk assessment Pre-inspection preparation On-site pharmacy inspection Report writing Quality assurance **Publication**

Registration of new premises

- 2 stage process drafted
- Draft application form developed
- Decision framework drafted for inspectors
- Engagement with NHSCB, Health Boards, sounding boards etc
- Ready for testing

Proportionate regulation

- Extensive engagement to understand what info is out there
- Pragmatic approach to start with, utilising:
 - Inspectors knowledge
 - Available and accessible information from others
- Testing risk assessment
- Testing varied frequencies

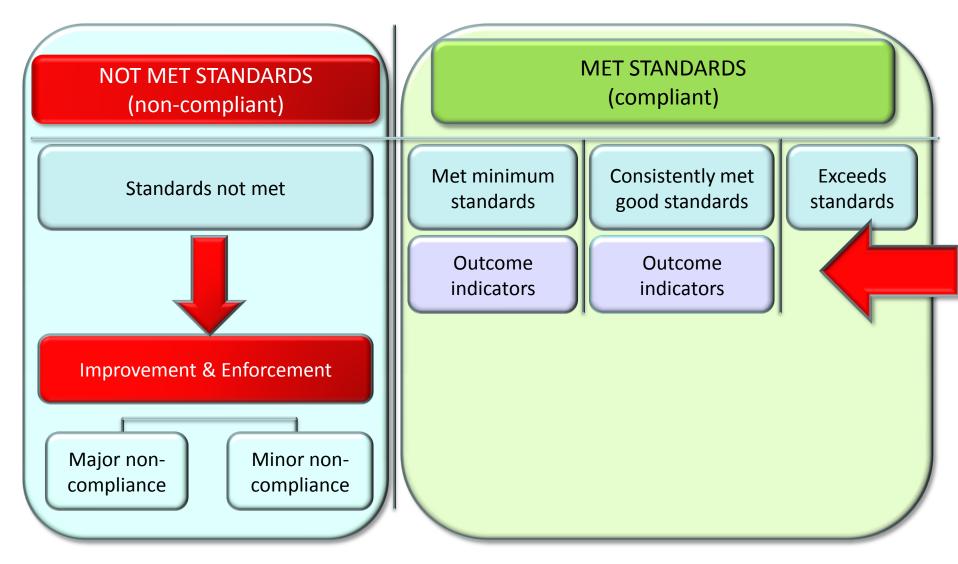
Pre-inspection prep

- Identified information that could be reviewed beforehand
- Tasks considered that could be carried out beforehand
- Ready for testing

On-site inspection

- Inspection decision framework
- Examples of outcome focussed indicators under minimum and good standards
- Extensive input from sounding boards
- Ready for testing

Inspection Decision Framework



Non-compliance criteria

Minor non-compliance

- 'Critical' standards are met and there is evidence of most other standards being met
- Most 'minimum standard' outcome indicators are being demonstrated
- Where standards are not met, the risks to patient or public safety are low (unlikely to occur and/or relatively low impact)
- Likely to be a range of issues, which taken together demonstrate non-compliance, e.g. Procedural weaknesses in record keeping, monitoring or review arrangements

Major non-compliance

- Evidence of a major breach of one or more of the 'critical' standards and/or significant regulatory responsibilities
- Number of standards <u>are not</u> being met
- Range of 'minimum standard' outcome indicators are not being demonstrated
- Risks to patient and public safety are moderate to high (likely to occur and/or with significant impact)
- Likely to be cases where we have identified systematic weaknesses

Example action plan

GPhC			Pharmacy action plan			
Standard not met	Reason	Remedial action to be taken	By when	By whom	Notification that standard met	Confirmed

Report writing

- 2 reports
 - High level public facing plain
 English summary report
 - Report for owner
- Engaged with public and patient groups
 - Content & format key findings, summary upfront, overall rating, clearly documented improvement plan if required
 - Tone & style short, concise wording without jargon, with bullet points

- Judgement terminology overall judgement and 3 sub categories terminology resonated
- Dissemination results
 displayed with date of last
 inspection, available internet,
 hard copy on request
- Engaged with sounding boards
- Prototype reports in draft
- Feedback from patient & public groups

Quality assurance

Investment in skills & knowledge of inspectors

Use of professional inspectors

QA checks

Relationship Manager

- Job profile drafted
- Review of corporate documents / arrangements by single person
- Formalised structured meetings – 3 a year
- Testing sites lined up