

PSNC Service Development Subcommittee Agenda

For the meeting to be held on Wednesday 6th February 2019

At 14 Hosier Lane, London, EC1A 9LQ

Commencing at 10.30am

Members: Richard Bradley, Clare Kerr, Sunil Kochhar, Prakash Patel, Faisal Tuddy, Gary Warner (Chairman)

1. Welcome from Chair
2. Apologies for absence
3. Conflicts or declaration of interest
4. Minutes of the last meeting ([Appendix SDS 01/02/2019](#))
5. Actions and Matters Arising

Action

6. SDS priority areas for 2019 ([Appendix SDS 02/02/2019](#))
7. Quality Payments – discussion on the future ([Confidential Appendix SDS 03/02/2019](#))
8. Seasonal Influenza Vaccination Advanced Service ([Appendix SDS 04/02/2019](#))
9. Developing a patient safety strategy for the NHS - Proposals for consultation ([Appendix SDS 05/02/2019](#))
10. GPhC Consultation on initial education and training standards for pharmacists ([Appendix SDS 06/02/2019](#))

Report

11. Update on NHS IT projects ([Appendix SDS 07/02/2019](#))
12. Update on the Falsified Medicines Directive ([Appendix SDS 08/02/2019](#))
13. Any other business

**Minutes of the PSNC Service Development Subcommittee meeting
held on Tuesday 9th October 2018
at Swindon Marriott Hotel, Pipers Way, Swindon, SN3 1SH**

Present: Richard Bradley, Sunil Kochhar, Prakash Patel, Faisal Tuddy, Gary Warner (Chair)

In attendance: David Broome, Mark Burdon, Alastair Buxton, Peter Cattee, Jack Cresswell, Ian Cubbin, Marc Donovan, Simon Dukes, Sam Fisher, Mark Griffiths, David Hamilton, Jas Heer, Gordon Hockey, Tricia Kennerley, Mike King, Andrew Lane, Zoe Long, Fin McCaul, Has Modi, Garry Myers, Bharat Patel, Indrajit Patel, Jay Patel, Janice Perkins, Sir Mike Pitt, Adrian Price, Sian Retallick, Suraj Shah, Anil Sharma, Rosie Taylor, Stephen Thomas

Item 1 – Welcome from Chair

Item 2 – Apologies for absence

2.1. Apologies for absence were received from Clare Kerr.

Item 3 – Conflicts or declaration of interest

3.1. No new conflicts of interest were declared.

Item 4 – Minutes of the last meeting

4.1. The minutes of the subcommittee meeting on 10th July 2018 were agreed.

Item 5 – Matters arising

5.1. None.

Action

Item 6 – Discussion on revision of PSNC’s service development proposals and options for quality measures which could be included in a revised CPCF

6.1. Alastair Buxton explained the background to this topic and provided an overview of the work undertaken so far.

6.2. After a thorough discussion, the proposed additions to the service development proposals were agreed; no further additions were proposed. It was agreed that additional points on mental health would be welcome additions to the proposals.

Action 1: Thoughts on additional proposals related to mental health to be sent to Alastair Buxton (all).

- 6.3. The subcommittee noted the inclusion of independent prescribing within the proposals and the strategic importance of this for future development of services.
- 6.4. The subcommittee concluded that the overall ambitious approach to service development described in the proposals was appropriate but noted that early priorities for the NHS were likely to be within the urgent care and public health areas. If such prioritisation is required, it would be helpful if a broad vision for future development of the contractual framework could also be agreed with NHS England and DHSC, so that contractors could more effectively plan for future developments.
- 6.5. No additions or amendments were proposed to the list of quality criteria/options set out in the agenda. The need to ensure discussions on quality were part of substantive negotiations and not separate was agreed. It was also agreed that there should ideally be a clear differentiation between quality indicators and service developments. Contractors should be given plenty of notice of forthcoming changes to the contractual framework, including any changes related to quality.

Item 7 – Revision of NMS and MUR consent requirements

- 7.1. The subcommittee agreed the proposed new consent requirements and wording for the consent forms with the new form / wording to be used as soon as practicable.

Action 2: Continue discussions with NHS England on this matter, aiming to reach agreement on this as soon as possible (AB).

Report

Item 8 – Update on NHS IT projects

Item 9 – Research on GP’s views on remote provision of pharmacy services

Item 10 – National clinical audit on flu vaccination for people with diabetes

Item 11 – Any other business

- 11.1. Quality Payments Scheme H2 2018/19 – Due to changes to the NHS BSA declaration portal for Quality Payments (this will now be provided through the NHS BSA Manage Your Service (MYS) portal rather than a Snap Survey) there is now the option for contractors to go back into their declaration after they have submitted it (within the declaration period) and make corrections. Previously once a declaration had been submitted, contractors could not amend it. There were potential risks with this approach, but the subcommittee agreed that the change should be implemented to provide maximum flexibility to contractors.
- 11.2 It was agreed that the NHS England QPS guidance should ideally be published by the end of October 2018.

Action 3: Communicate the subcommittee's views on these matters to NHS England and to agree a final position for inclusion in the QPS guidance (RT).

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Subject	SDS priority areas for 2019
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	This paper contains suggested priorities for the work of the Services Team and SDS during 2019, for consideration by the Subcommittee.
Proposed action	Consider and agree priorities for the work of the Services Team and SDS during 2019.
Author of the paper	Alastair Buxton

Introduction

This paper contains suggested priorities for the work of the Services Team and SDS during 2019, for consideration by the Subcommittee. Some more specific priorities may emerge during the year, but these are likely to be driven by the direction taken in the negotiations for 2019/20, so at this point, they cannot be easily predicted.

Pharmacy Services

1. Prepare for and support negotiations with DHSC and NHS England – the detail will be dependent on the negotiating mandate, but provisional priorities are:
 - Agreeing a new quality scheme;
 - Recommissioning of the flu vaccination service;
 - Ensuring NUMSAS is substantively commissioned in an effective manner; and
 - Ensuring DMIRS rollout and development (GP referrals) is undertaken in a way that works for contractors.
2. Support contractors and LPCs to implement any changes to the CPCF;
3. Develop PSNC's support to help LPCs and contractors to effectively engage with the evolving local NHS structures, particularly Primary Care Networks (linked responsibility with LCS);
4. Develop PSNC's support for local service development, commissioning and implementation. This would include the ongoing work on developing template service specifications, business cases and other resources.

Note: The main points in this list are in suggested priority order and work on the first three points would likely need to be prioritised over point 4.

Community pharmacy IT

1. Work with NHS Digital and contractors within the EPS phase 4 pilot to ensure learning is identified from the pilot and outstanding EPS issues are addressed before any rollout of phase 4;
2. Work with NHS Digital and NHS England to ensure their digital medicines workstreams are supportive of and work for pharmacy contractors, particularly the testing and rollout of Real-Time Exemption Checking and work on interoperability and data sharing between pharmacy and general practice; and

3. Support contractors with the implementation of FMD and secure funding from DHSC/NHS England (linked responsibility on funding with FunCon).

Note: some of the activity on IT will be driven via our joint Community Pharmacy IT Group workstreams.

Subcommittee action

Consider and agree priorities for the work of the Services Team and SDS during 2019.

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Subject	Seasonal Influenza Vaccination Advanced Service
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	This paper provides a brief report on the current season's flu vaccination service, discussions with PHE, NHS England and other stakeholders on lessons learned from this season and changes to vaccine selection for the 2019/20 season.
Proposed action	Consider whether any changes are necessary to the service for the 2019/20 season.
Authors of the paper	Alastair Buxton

Review of the current programme

Statistics on the current season are available on [the PSNC website](#), but the broad picture is that we are on track to surpass the number of vaccines administered in 2017/18. However, the year on year growth in the number of vaccines administered by pharmacies is likely to be much smaller than that seen in recent years. It is assumed that this suppression in the growth rate is largely a result of the complexities of vaccine supply seen this season.

In early January, the aTIV working group, which comprises representatives of DHSC, NHS England, PHE, PSNC and GPC, met to review lessons learned from the current season, which could inform the development of the programme in 2019/20. A wide range of issues were discussed, including the delays in publication of documentation and guidance by PHE and NHS England, the problems with ordering aTIV and lost orders, and the phased delivery schedule.

On a more positive note, there was a recognition that while it had been necessary for the working group to tackle many challenging issues, it had led to better collaboration and coordination of the communications and guidance provided to the professions than had been seen in previous years. Therefore, all parties have agreed that a similar operational working group will be put in place for future programmes, with meetings likely to commence in February.

There was also a general sense that there had been fewer local disputes between pharmacies and general practices than had been seen in previous years, with several good examples of active collaboration being seen, notably the joint work undertaken by the LPCs and LMC across Wessex.

Amendment of the community pharmacy service

Many changes to the flu vaccination service, which had been requested by contractors and LPCs, were agreed with NHS England for the 2018/19 service. So far, the Services Team has not received any further feedback from contractors or LPCs on other changes which could be made to the service.

NHS England's regional public health leads have asked that in future there should be a route via which they can be informed in a timely manner of which pharmacies are providing the service; this information ceased to be available to them with the removal, this season, of the NHSBSA service sign-up requirement.

One potential change to the service would be to request the removal of the obligation to ask patients to complete the patient satisfaction questionnaire. This would save contractors some time, but it would also mean that we would not have access to the data to demonstrate the overwhelmingly positive assessment of the service given by most patients.

It should also be noted that unless there is a no-deal Brexit, vaccines will be FMD compliant in 2019/20, so they will need to be decommissioned prior to administration; this will increase costs and consequently should be discussed with NHS England.

Subcommittee action

Consider whether there are any changes to the 2019/20 flu vaccination service that PSNC should seek to agree with NHS England.

Vaccine selection for 2019/20

Following discussions over the last few months at the meetings of the aTIV working group, there was a clear recognition from PHE and NHS England of the importance of being able to provide earlier guidance to pharmacies and general practices on the vaccines to be selected for the forthcoming season. Initial guidance was issued to contractors in mid-November 2018 and following the licensing of two new types of vaccine, [final guidance](#) has just been issued by PHE and NHS England.

Contractors will be able to use the new cell-grown QIV, but the high dose TIV will not be funded by the NHS.

Annex A

Product	Suitable for use in clinical at-risk / eligible adults under 65 years	Suitable for use in adults 65 years and over	Licensure status	Recommended by NHS England	NHS Cost per dose <small>*See link for further detail on vaccines, cost and supplier</small>
Standard trivalent vaccines (TIVe)	NO	NO	Licensed	NO	NA
Standard egg-grown quadrivalent vaccines (QIVe)	YES	NO	Licensed	YES	Products available at £8.00 and £9.94
Adjuvanted trivalent vaccine (aTIV)	NO	YES	Licensed (for those aged 65 years and over)	YES	£9.79
Cell-grown quadrivalent vaccine (QIVc)	YES	YES	Licensed (aged 9 years and over)	YES	£9.94
High-dose trivalent vaccine (TIV-HD)	NO	YES	Licensed (for those aged 65 years and over)	NO	£20.00

*Prices and suppliers of the vaccines can be found here:
<https://bnf.nice.org.uk/medicinal-forms/influenza-vaccine.html>

We would ask providers to be cognisant of the relative costs to the NHS of the range of vaccines available in the market when ordering vaccines for the 2019/20 season.

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Subject	Developing a patient safety strategy for the NHS - Proposals for consultation
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	This paper summarises an NHS Improvement consultation document on the development of a patient safety strategy for the NHS.
Proposed actions	<p>Consider the proposals within the paper and the questions posed and suggest points which should be made in a response to NHS Improvement.</p> <p>Consider whether a joint response to this consultation with other community pharmacy organisations may be appropriate.</p>
Author of the paper	Zainab Al-Kharsan

Developing a patient safety strategy for the NHS

In December 2018, NHS Improvement published [proposals](#) for a national patient safety strategy. It is relevant to all parts of the NHS, be that physical or mental health care, in or out of hospital and primary care. While some measures are already underway, or represent an evolution of current work, some are new and wide-reaching. The consultation is open until 15th February 2019.

The proposals have been informed by learnings from engagement around the NHS Long Term Plan and various reviews undertaken by the Care Quality Commission (CQC), including their review of Never Events.

The National Reporting and Learning System remains a valuable resource for the NHS, but to benefit from technological advances since its launch, it is being replaced with the Patient Safety Incident Management System (PSIMS), which will use new technology, such as artificial intelligence and machine learning, to better support the work to understand and reduce risks.

Proposed aims

The proposed strategy has three aims for the NHS. These are for the NHS to:

- be world leading at drawing **insight** from multiple sources of patient safety information;
- give staff at all levels the skills and support they need to help improve patient safety, so they can be the **infrastructure** for safety improvement, working with patients and partner organisations; and
- decrease harm in key areas by 50% by 2023/24 and beyond through specific patient safety **initiatives**.

Proposed principles

1. A just culture

This principle focusses on the importance of changing systems and processes to make it easier for people to do their jobs safely, rather than punish people when they make mistakes. Whilst the vast majority of people in healthcare intend to do a good job and to help others, a few people are deliberately malicious or wilfully negligent. Action should be taken to protect patients and wider society. The safety response is separate from any sanction against the individual however and focus should be on improving systems and processes to reduce the chances of these rare individuals harming patients.

2. Openness and transparency

This principle is to acknowledge that things can, and do, go wrong and that things must change. Everyone should be supported to talk about incidents and be open and transparent, including with the patients, family members and carers who are affected.

3. Continuous improvement

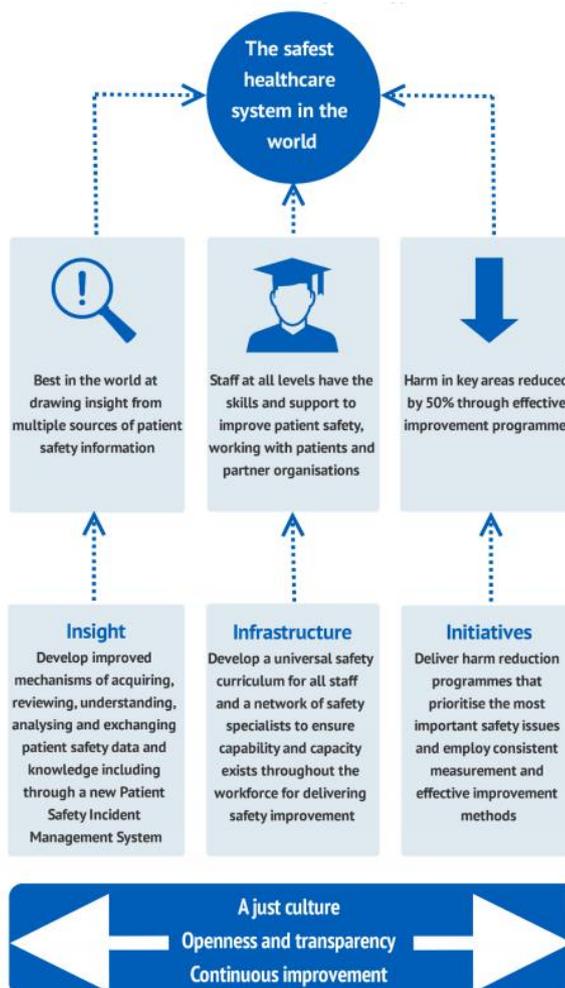
Improving patient safety is not a problem to be solved once and for all. Instead, working to enhance the reliability of how healthcare is provided should be a constant aim for everyone in healthcare. The science of quality improvement must be applied to this work.

Staff and patients also need to be empowered to identify and then act on those areas where we can improve. This applies across primary and community care as much as across acute and mental health care.

Q1: Principles

- A. Do you agree with these aims and principles? Would you suggest any others?
- B. What do you think is inhibiting the development of a just safety culture?
- C. Are you aware of [A just culture guide](#)?
- D. What could be done to help further develop a just culture?
- E. What more should be done to support openness and transparency?
- F. How can we further support continuous safety improvement?

The proposal



Insight

The new PSIMS will give NHS Improvement the ability to interrogate data from the NRLS more robustly and explore enhancing what goes well in healthcare rather than preventing what goes wrong – this concept is being described as [Safety II](#). The new system is also intended to make reporting easier and more rewarding.

The new National Patient Safety Alerts Committee (NaPSAC) is leading work on how NHS Improvement provides safety critical advice and guidance to the NHS by redesigning the format of and standardising the criteria for the development of patient safety alerts in collaboration with the Medicines and Healthcare products Regulatory Agency.

NHS Improvement will use the evidence gathered as part of the review of the Serious Incident Framework and work with the Healthcare Safety Investigation Branch to improve the quality of safety investigation and help providers and local systems generate their own insight.

Closer working between NHS England and NHS Improvement will provide the opportunity to ensure data is used in a consistent way across the NHS to understand patient safety.

Q2: Insight

- A. Do you agree with these proposals? Please give the reasons for your answer
- B. Would you suggest anything different or is there anything you would add?

Infrastructure

Progress to encourage improvement in systems is being held back by insufficient patient safety education, knowledge, skills and understanding at all levels and in all staff groups. Concerns have been found around insufficient patient safety understanding, a limited ability for those who create patient safety alerts to work directly with senior safety leads and inconsistent approaches across NHS England.

NHS Improvement is proposing a cross-system development of a shared and consistent patient safety curriculum for all current and future NHS staff that can be appropriately tailored and which can also be used to train interested patients and lay representatives.

Additionally, it also proposes the development of a network of senior patient safety specialists in providers and local systems to become the backbone of patient safety in the NHS. The proposal is also to have these specialists in NHS regional teams, regulators and commissioners to ensure consistency of approach.

The document states that these roles should not be filled by recruiting new staff, but rather by identifying existing staff who are already working in safety-related roles, be they nurses, doctors, pharmacists, managers or allied health professionals, and who can be supported to become these skilled specialists.

NHS Improvement will also help the NHS recruit patient advocates for safety to ensure patients are heard throughout the system.

Finally, there is a proposal to establish a dedicated patient safety support team that can be assigned to organisations that are particularly challenged in relation to safety.

Q3: Infrastructure

- A. Do you agree with these proposals? Please give the reasons for your answer.
- B. Would you suggest anything different; would you add anything?
- C. Which areas do you think a national patient safety curriculum should cover?
- D. How should training be delivered?
- E. What skills and knowledge should patient safety specialists have?

Initiatives

NHS Improvement proposes reducing the amount of harm in key areas of patient safety by 50% by 2023/24 and beyond. Priority will be assigned to programmes where the most significant harm is seen, litigation costs are highest, unwarranted variation is greatest and evidence-based interventions are known to mitigate risk. Guidance will be provided by experts such as professional associations, royal colleges, frontline clinicians, patient representatives and the [Patient Safety Translational Research Centres](#).

The main route for delivering these initiatives would be the [Patient Safety Collaboratives \(PSC\) programme](#) which will be continued with a more consistent and structured approach. A key part of this will be better alignment of the PSC programme with the seven NHS regional teams that are being created as part of NHS Improvement's and NHS England's commitment to integrate regional structures. The PSC programme is also looking at spread and adoption of successful safety interventions.

Significant new work on medication safety, aligned with the World Health Organization's [Medication Without Harm challenge](#), is being planned. Whilst the interventions are not yet decided, it is already known which medicines, patients and processes are highest risk and that there is a need to intervene to reduce harm in these areas.

It is also intended that the PSC programme links to work on anti-microbial resistance, with plans on roll-out of electronic prescribing systems set to help. Alongside this, there are ongoing efforts to improve infection prevention and control, including reducing cases of healthcare-associated Gram-negative bloodstream infections by 50% by March 2024.

Other areas of focus include:

- Work on maternal and neonatal health;

- Continuing to facilitate the falls collaborative programme and offer bespoke support to providers with improvement needs;
- Further improvement initiatives on nutritional care to support the national wound care strategy;
- Address the high litigation costs in primary and secondary care; and
- Continue to mitigate risks, such as for Never Events, and develop a toolbox for preventing each type.

Q4: Initiatives

- A. Do you agree with these proposals? Please give the reasons for your answer.
- B. Would you suggest anything different or do you have anything to add?
- C. What are the most effective improvement approaches and delivery model?
- D. What approaches for adoption and spread are most effective?
- E. How should we achieve sustainability and define success?

Subcommittee actions

Consider the proposals within the paper and the questions posed and suggest points which should be made in a response to NHS Improvement.

Consider whether a joint response to this consultation with other community pharmacy organisations may be appropriate.

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Subject	GPhC consultation on initial education and training standards for pharmacists
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	<p>This paper provides a brief overview of the GPhC's proposals for changes to the initial education and training standards for pharmacists. This includes setting integrated standards for the full period of initial education and training, rather than the current separate undergraduate and preregistration requirements.</p> <p>More detailed consideration of the proposals will be required following the meeting of the subcommittee to inform the development of PSNC's response to the consultation.</p>
Proposed actions	<p>Provide any initial thoughts on the GPhC's proposals.</p> <p>Identify Committee members who would like to provide detailed feedback on the proposals, to inform PSNC's response</p>
Author of the paper	Alastair Buxton

Introduction

In January 2019, the General Pharmaceutical Council (GPhC) launched a [Consultation on initial education and training standards for pharmacists](#); the consultation closes on 3rd April 2019.

The GPhC state that pharmacists' roles are evolving quickly in response to rapid changes in healthcare and pharmacy practice; initial education and training also needs to evolve to reflect these changes so that pharmacists are equipped with the skills they need to develop new services.

The consultation proposes modernisation of the initial education and training of pharmacists. This is to take account of recent developments in the delivery of initial education and training, and to give pharmacists the knowledge, attitudes and behaviours they will need to be prepared for future practice.

The most important change is that GPhC are proposing to set integrated standards for the full period of initial education and training. At the moment, the most common form of initial education and training for pharmacists in Great Britain is a four-year MPharm degree accredited by the GPhC, followed by 52 weeks of pre-registration training in one or more sectors of practice. GPhC currently set standards and learning outcomes for the MPharm degree and then separate performance standards and learning outcomes for the pre-registration year.

GPhC think that now is the time to bring pharmacist initial education and training (IET) into line with other clinical healthcare professions by integrating academic study and workplace experience. They propose to have one set of standards and learning outcomes that cover the full period of initial education and training.

The proposed changes to the standards

It is proposed that the learning outcomes are focused on four themes:

- person-centred care;
- professionalism;
- professional knowledge and skills; and
- collaboration.

The document explains that the standards are more heavily focused on clinical skills and on the importance of communicating effectively with people. This includes involving people in decisions about their care as well as advising them clearly and confidently about their use of medicines. It also includes making sure that students learn skills relating to prescribing such as consultation and physical examination.

GPhC believe it is essential that pharmacy students have a greater involvement with, and exposure to, other health and care professionals, starting from the early stages of their education and training. They see this increased focus on clinical and communication skills and multi-professional learning as essential to equipping pharmacists with the flexibility they will

need in the future. They also believe it will develop the confidence of pharmacists to play a leading role in person-centred care – something which has been consistently raised with them while they have been developing these new standards.

GPhC do not, at this stage, think that newly qualified pharmacists will be ready to practise immediately as independent prescribers. However, they do think it is realistic for IET to deliver the knowledge and skills needed for independent prescribing.

GPhC propose to strengthen the current selection and admission standard. Education providers will have to assess the professional skills and attributes of prospective students as well as their academic qualifications. By that GPhC mean their:

- interest in person-centred care;
- ability to work with other people;
- professionalism;
- problem-solving abilities; and
- numeracy skills.

To help achieve this, GPhC will also require providers to build interactive activities into their admissions processes, for example multiple mini interviews and group work.

GPhC will be expecting education providers to have clear criteria for deciding when it is appropriate to admit students who have not achieved the advertised grades, in line with agreed institutional policies. They will also expect evidence showing the level of monitoring and support provided to those students.

Schools of pharmacy will have to have effective measures in place to make sure that only people who have demonstrated over the full period of initial education and training that they can achieve the standard required for registration then go on to graduate. Designated learning in practice supervisors (currently known as pre-reg tutors) will also not be able to sign off student pharmacists if they have not met the learning outcomes of learning in practice.

The following bodies will work together to implement the new IET standards:

- schools of pharmacy
- education and training providers, and
- national education and training commissioning/quality assurance (QA) organisations (in England - Health Education England)

The standards are in two parts:

Part 1: IET standards for pharmacists – learning outcomes

This part includes the knowledge, skills, understanding and professional behaviours a student pharmacist must demonstrate at the end of a programme leading to registration with the GPhC.

Part 2: IET standards for pharmacists – standards for providers

This part includes the requirements for a programme delivering the learning outcomes in part 1.

The detailed standards are set out in the [consultation document](#).

Subcommittee actions

Provide any initial thoughts on the GPhC's proposals.

Identify Committee members who would like to provide detailed feedback on the proposals, to inform PSNC's response (it is also hoped that there can be some discussions on this topic with the other community pharmacy bodies ahead of the drafting of our response).

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Subject	Update on NHS IT projects
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	<p>This report provides an update on the following NHS IT projects: NHS App, EPS Phase 4, EPS Controlled Drugs and Real-time Exemption Checking.</p> <p>More detailed information on these projects was included in the October 2018 SDS agenda.</p>
Proposed action	None
Author of the paper	Daniel Ah-Thion

NHS App

Following a public beta testing phase, the [NHS App](#) is being gradually rolled out across England during 2019. Some of the NHS App functionality is similar to the GP online services which have been available for some time. Individual GP practices will need to review some of their system settings before patients can access the full NHS App functionalities. NHS Digital have said that most surgeries could go live between April and June 2019.

PSNC and the CP ITG will continue work with the NHS App team and NHS England's Empower the Person domain to influence the future development of the app, e.g. including functionality so patients can set their EPS nominations via the app.

EPS Phase 4

NHS Digital began piloting [EPS Phase 4](#) at the end of November 2018. Initially, four GP practices were granted ability to use EPS for patients without an EPS nomination: patients are given a paper Phase 4 token with a scannable barcode instead of a signed paper prescription.

The pilot sites are within Greater Manchester, Essex, south-east London and Devon. Pilot prescribers have successfully issued hundreds of Phase 4 prescriptions. NHS Digital observed that printer routing guidance could be developed to further support practice staff sending tokens to the most appropriate printer within the building.

Work will continue with NHS Digital to support the pilot and to identify learnings from the pharmacies involved.

EPS Controlled Drugs (CDs)

From early October 2018, NHS Digital began to pilot the prescribing and dispensing [of EPS Schedule 2 and 3 Controlled Drugs](#) in a small number of GP practices with EMIS or Vision. The project aim is to demonstrate that EPS CD prescribing capability is safe and appropriate to be rolled out across the country. Within the pilot sites, prescriptions have been processed successfully at the prescriber and pharmacy end.

It is hoped that piloting with a small number of GP practices using the SystemOne (TPP) system can start in late January 2019.

Feedback from GP practices, community pharmacies, PSNC and other stakeholders will be used to refine the process prior to further roll-out. If the pilot is successful, EPS will be deployed to all Vision, EMIS and TPP sites.

Evolution (Microtest) are developing CD prescribing capability for testing during early 2019.

Real-time exemption checking (RTEC)

The [RTEC](#) system will be rolled out in phases. Phase One will comprise maternity, medical, pre-payment, low income scheme and HMRC exemptions.

In December 2018, the RTEC Steering Group were given a demonstration of the functionality in the early adopter PMR system, which appeared to fit well within the existing dispensing/label generation process. The first RTEC piloting is scheduled for mid to late February 2019 at the earliest. Pilot areas include Manchester and north Leeds. If the pilot goes well, further rollout for pharmacy contractors that use the early adopter PMR system is expected during the following months.

PSNC will continue to work with NHS Digital, DHSC and NHS England on the planning for this change in process within pharmacies. We are also continuing to discuss with DHSC the need for maternity exemptions to be visible to pharmacy staff within the RTEC message, but it is looking less likely that this will be agreed to.

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Subject	Falsified Medicines Directive (FMD)
Date of meeting	6th February 2019
Committee/Subcommittee	SDS
Status	Public
Overview	This paper provides a brief update on progress with the implementation of FMD.
Proposed action	None
Author of the paper	Alastair Buxton

Ongoing activity

The UK Community Pharmacy FMD Working Group has continued to meet on a regular basis with SecurMed, DHSC, MHRA, GPhC, system suppliers and other stakeholders to monitor progress on the path to implementation of FMD and to clarify requirements and guidance for contractors.

A recent meeting was held with several FMD working group members and members of the Healthcare Distribution Association (HDA), to explore the issues around non-compliant medicines, which can still be supplied, and the risks that contractors seek to return these to wholesalers for credit. Further guidance for contractors is being developed on this topic and which packs need to be scanned and those that do not. It is hoped this can be distributed to pharmacies by HDA members.

Brexit and legislation

The uncertainty about Brexit means that the long-term connection of the UK FMD hub to the central European database, where all manufacturers' data is uploaded, cannot be guaranteed. If there is a no-deal Brexit, DHSC will lay legislation, which has already been drafted, to remove the legal obligation for actors in the medicines supply chain to comply with FMD.

MHRA has also responded to the public consultation on various flexibilities that member states can apply to the implementation of FMD and on proposals for the sanctions to be applied, where non-compliance is identified.

The approach to regulation will start with GPhC inspections, viewing compliance with FMD, as a part of their wider examination of the safe practice of pharmacy. Where significant breaches are identified, the MHRA will have the power to use civil sanctions in the first instance, with the application of criminal sanctions being reserved for the worst cases, where fraud is involved. Regulations have been laid in Parliament to insert the sanctions into the Human Medicines Regulations and MHRA and GPhC have recently issued a joint statement to explain their approach to regulation of FMD compliance. Further information on all these points can be found on the [FMD Source](#) website.

Communications and support for contractors

The [FMD Source](#) website has been developed on behalf of the FMD working group by PSNC and we are making regular updates, with the site's content last fully reviewed and updated in mid-January.

The website contains a full explanation of FMD, practical advice on implementation, information on the current situation and Brexit, and extensive FAQs. Alongside this, other bodies, such as the NPA are developing complementary resources for contractors, such as updated SOP templates.

PSNC has worked with the NPA comms team to draft a statement on the current state of play and to provide some reassurance to contractors on the approach which will be taken to enforcement of the provisions; this should be published in the next few days.

Progress by SecurMed and system suppliers

SecurMed are seeing an increase in organisations registering to connect to the UK hub as the deadline for implementation on 9th February rapidly approaches. They have supplied data as of 22nd January, indicating that 2,109 pharmacy sites had been successfully registered and 34.5 million individual packs had been loaded into the system.

Standalone FMD systems and PMR systems are being installed in pharmacies across the country to undertake initial testing in the live environment and products have now been successfully decommissioned in several community pharmacies.

Funding for contractors

A draft cost model has been circulated for review to FunCon members and others with a special interest in FMD; feedback on the costings within the spreadsheet and the assumptions made in the model is being provided which will inform the creation of a second iteration of the spreadsheet.

Discussions on funding will be part of the forthcoming negotiations for 2019/20.

Task	Estima ted time (mins)	Task completed by	Average number of	Costs	Source of figure	Freque ncy	Internal comments
Initial set-up costs: PMR vs standalone solution							
<i>Scenario 1 of 2: PMR/Integrated solution</i>							
• Uplift one-off cost to setup	150.00	Phising from a range of suppliers	one-off	£150.00	PFSC	one-off	
• Additional computer terminal (including screen)	£800.00	Phising from a range of suppliers	one-off	£800.00	PFSC	one-off	Three scanners per pharmacy
• Handheld scanners	£450.00	Phising from a range of suppliers	one-off	£450.00	PFSC	one-off	
Sub-total				£1,400.00			
<i>Scenario 2 of 2: Standalone solution</i>							
• Uplift one-off cost to setup	150.00	Phising from a range of suppliers	one-off	£150.00	PFSC	one-off	
• Mobile device with separate scanner	£350.00	Phising from a range of suppliers	one-off	£350.00	PFSC	one-off	One device and scanner per pharmacy
Sub-total				£500.00			
Initial set-up costs: Relates to both PMR or standalone solution							
<i>Planning for business change year 1</i>							
• Time for Superintendent Pharmacist to revise SOPs	180	Superintendent Pharmacist	1	£94.50		one-off	
• Time for Superintendent Pharmacist to revise business continuity plan to incorporate FMD	30	Superintendent Pharmacist	1	£15.75		one-off	
• Time to train members of staff on below during Year 1, and discuss changes to SOPs	120	Superintendent Pharmacist	1	£63.00		one-off	
• Cost of printing and distributing training				£20.00		one-off	
<i>Time for staff to train and consider revised processes:</i>							
Training time	90	Pharmacist	197	£93.08		one-off	Average no. pharmacists per pharmacy from HEE workforce survey results = 197
Training time	90	Pharmacy Technician	638	£203.37		one-off	Average no. staff per pharmacy from HEE workforce survey results (ie. PT, ACT, Pharmacy Technician) = 638
Training time	90	Dispenser	304	£51.71		one-off	Average no. staff per pharmacy from HEE workforce survey results (ie. Trainee Dispenser combined) = 304
Training time	30	Medicine Counter Assistant (MCA)	2	£8.19		one-off	Average no. staff per pharmacy from HEE workforce survey results (ie. Trainee MCA combined) = 2.00
<i>Prepare patient materials/communications necessary</i>							
• Time to read and prepare patient materials	20	Superintendent Pharmacist	1	£9.50		one-off	Question for Committee - is it likely that contractors will distribute/prepare patient comms?
• Cost of obtaining/printing patient materials				£3.00		one-off	
Sub-total				£3.00			
Total: Setup cost: PMR/FMD IT solution				£1,903.00		one-off	

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