National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from NWSSP Procurement, SMTL, Mr Alun Tomkinson et al – MT 20

Inquiry into access to medical technologies in Wales

On behalf of NWSSP Procurement, SMTL, Mr Alun Tomkinson and others.

October 2013

"A joined up approach to commissioning."

Introduction

1. The Procurement of medical devices for the NHS in Wales is managed by the Procurement division of the Shared Services Partnership. This provides a collaborative approach across the ten Health organisations in Wales, which has a history going back over 30 years of working in this way. In the spirit of working in partnership, this response is supported by a number of leading individuals from within the NHS who are listed in Appendix 1.

2. The medical device regulatory process does not always ensure devices are fit for purpose and safe in clinical use, and evidence of efficacy is frequently poor. Clinicians wishing to assess devices clinically may expose patients to risk, especially as errors caused by inadequate usability have become increasingly common. In 2012, the BMJ[1] noted that safety of medical devices "i*s dealt with in an unsatisfactory way, and efficacy not at all",* and that *"a new system that improved scientific evidence of safety, required evidence of efficacy, ... would be well worth considering.*"

An MHRA (Medicines and Healthcare products Regulatory Agency) report by Campbell[2] also stated:

> *"The evidence on safety and efficacy of new devices and new procedures at the time they are introduced into UK practice is very variable. Some have been evaluated in well designed studies but more commonly the evidence base is modest or poor."*

3. These are not theoretical concerns. Wales has its own experience of poor quality devices causing clinical harm - when the move to SEAC (Spongiform Encephalopathy Advisory Committee) mandated single-use tonsillectomy instruments took place, Welsh NHS return-to-theatre rates from post-operative bleeding increased from 1.5% to 4.4%[3]. A collaboration of procurement, clinician engagement and laboratory testing at SMTL (Surgical Materials Testing Laboratory) brought the situation back under control.

4. The problem is recognised internationally - from 2005 through 2009, the FDA (Food and Drugs Administration) received approximately 56,000 reports of adverse events[4] associated with the use of infusion pumps, including numerous injuries and deaths. 14 of these reports were Class I – situations in which there is a reasonable probability that use of the recalled device would cause serious adverse health consequences or death.

1 BMJ.

2 http://www.mhra.gov.uk/Howweregulate/Devices/Devicesregulatorynews/CON082083

3 Clin

4

5. The problem is also recognised outside the UK. The Liaison Officer to the European Standards technical committee CEN/TC 205/WG 3 (which deals with medical gloves) reported recently that:

> *Currently, no regulatory bodies in EU confirm the conformity assessment process of manufacturers of examination gloves, nor do they validate that all the claims made for a product can be substantiated.*

6. Within the Welsh NHS, there is already a well coordinated and respected approach to medicines through the AWMSG (All Wales Medicines Strategy Group). We believe that a similar approach for devices and medical technology would build on our experience in this area, delivering significant benefits, increasing clinician engagement, and enhancing patient safety.

Background

7. In considering our response to the request for comments it was felt that it would be important to provide a framework against which the response should be seen. The following were felt to be key areas in this:-

   I. Any new or different product should be judged against a demonstrable improvement in the clinical outcome for the patient and or a change in the clinical pathway.

   II. Risk Pool costs are escalating , with claims of £60m last year, forecast £71m 2013/14 , with in excess of £500m open liabilities being reviewed. Discussions with Welsh Risk Pool have identified cases where poor quality and/or poorly designed medical devices have caused patient injury leading to significant settlements. For example, inappropriate choice of holders (stirrups etc) for a Lithotomy procedure has lead to a settlement of £50,000 damages and £12,000 costs.

   III. CE marking has mixed confidence among clinicians;

   IV. Financial pressures and a growing elderly population are dictating increased efficiency in interventions, reduced costs of ownership and purchase, shorter in-patient stays, and better clinical outcomes. Better or improved Value for Money for NHS Wales is therefore vital.

   V. It is recognised that a more flexible approach to budget setting and management across directorates and indeed organisations might well be required, including whole-of-life costings for expenditure and non-silo budgets – a case of “think globally, act locally”.

   VI. Clinician engagement with device/technology procurement could and should be better; Wales has a very inclusive and collaborative approach to Procurement across all its categories. This is particularly important where for over 30 years we have had various mechanisms for working with professional clinical staff, and through this process managed to achieve far more standardisation of products than our English counterparts. This can, however be improved.

   VII. The environment of “Comply or Explain” - if the Health Boards are not conforming to contracts, best practice, guidance and advice, we should explain why those decisions have been taken. To do that, we need better information and better structures;

   VIII. Industry often complain about the lack of access to clinicians, especially their belief that the NHS is slow to adopt innovative products. They are often not clear about structures and certainly struggle with the differences between the English Health Care system and that which exists within Wales, and the “Celtic fringe”. Solutions and or products which can ultimately have a positive impact on the Welsh economy can form the basis for creating wealth employment opportunities and ultimately inward investment.

Horizon Scanning

8. There is presently no coordinated horizon scanning linked with the procurement of medical devices and new technology within the NHS. This is an area of opportunity, but again requires coordination.

9. A horizon scanning programme is in existence at the University of Birmingham, the *National Institute*

for Health Research (NIHR) *Horizon Scanning Centre*, which also hosts the *Secretariat for EuroScan* – the International information network on new and emerging health technologies

10. There are other data sources available which, if used appropriately, could help identify areas of focus:, including MHRA adverse incidents, the NRLS (National Reporting and Learning System), Welsh Risk Pool claims, SMTL defect reports, Procurement expenditure & adoption and NICE (National Institute for Health and Care Excellence) guidance and appraisals undertaken by CEDAR (Healthcare Technology Research Centre) in Cardiff & Vale Health Board

11. The Welsh NHS could and should make better use of the information provided by these centres and databases. However, at present, individual Health Boards and Trusts are left to make their own judgements, and in many cases have neither the expertise or the resource to link up this data. A coordinating body which draws together the research from these sources whilst also understanding and identifying Welsh unmet needs, could identify technologies which should be assessed for the Welsh NHS.

Assessing the potential benefits of new or alternative technologies

12. Once the areas of focus have been identified, the task of assessing which technology may deliver the required benefits can be addressed.

13. There are a number of groupings who should be involved in this process, including NHS clinicians, procurement, academia, trade bodies, and other interested organisations such as MediWales. The aim of this exercise would be to:

- benefit patient safety, by filtering and sieving out devices and technologies which are inappropriate to prevent patient exposure to risks. This may involve a multi-step screening process;
- assess the potential risks of medical devices. This will tie together concrete financial and clinical risks (for example, linking up Welsh Risk Pool data with NRLS, SMTL and MHRA incident data), and evaluating and introducing device adoption strategies such as those used in the “Beyond Compliance” programme.

14. We believe that adoption and adaption of the “Beyond Compliance” strategy could be useful. The “Beyond Compliance” programme uses a risk-based strategy, rating the risk of the device (orthopaedic implants) from 1 (low risk) to 4 (high risk), and recommending introduction rates (unrestricted through to limited), alongside a monitoring process (which may include Notified Body involvement for the highest risks).

15. This would then link into coordination of the selection and pre-procurement process, involving credible individuals and processes to reduce risk and gain clinician engagement. It should include:

    - Laboratory testing
    - Clinical engagement and assessment, including Human Factors and usability studies.

16. Assessment of devices in patients may expose patients to risk. Errors caused by inadequate usability have become an increasing cause for concern. Usability testing by clinicians, in a non-clinical environment similar to that used by the aircraft industry, enables safety and effectiveness criteria to be assessed.

17. High reliability industries such as the airline, oil, military and nuclear industries are *“safety aware and simulation savvy”*. In the medical device arena, simulation testing gives the opportunity to amplify real patient experience, and to introduce artificially contrived situations, which replicate the rare but difficult clinical situations when devices are most likely to fail or cause problems, uncovering potential issues which may not be discovered during the 'average' clinical assessment. It also has the great advantage of uncovering design flaws and other issues in a safe environment, reducing the risk of patient exposure.

18. However, the use of human factors assessments is not routine in the medical device field, and we are unaware of any routine use in the procurement of safety assured devices within the UK or elsewhere.

Swansea University have expertise in human factors assessment of medical devices such as infusion pumps, and this could be leveraged to provide evidence to Welsh NHS procurement, enabling the purchase of safety assured devices and technology.

19. The Surgical Materials Testing Laboratory (SMTL) in Princess of Wales Hospital, Bridgend, is funded by WHSSC (Welsh Health Specialised Services Committee) to test and provide technical information on medical devices. At present they deal with a range of commodity devices such as gloves, gowns, masks, dressings and surgical instruments, but there is an opportunity to expand their role regarding the technical aspects of medical device assessment.

20. There should also be a monitoring or measurement programme associated with these decisions to check whether clinical benefits are being delivered, risk is being mitigated; and to undertake further interventions if necessary;

21. As with most of our proposals, we envisage these assessments would feed into a structured Procurement process, to drive and manage the change once the intervention is assessed and approved.

Health Economics

22. The assessment of value for money is a key component within any commissioning framework. The use of cost-effectiveness techniques to evaluate the relative costs and benefits of medical technologies is a burgeoning area and one that NICE is increasingly getting involved with. **It is essential to ensure that resources committed to the procurement of medical technologies provide a level of return that is at least commensurate with the use of those resources in alternative or even competing areas within the health care environment.**

23. There is a danger in adopting novel technologies which can be mitigated by appropriate cost-effectiveness analysis, which relates the additional costs incurred in utilising the new technology to the additional benefits gained from its use. The metric(s) used to measure and value benefit can be based on health care effects, utility (quality of life) or monetary gains. The resultant ratio can be benchmarked to determine whether the technology represents value for money. Sensitivity analyses are incorporated to assess the degree to which parameter variation influences the findings of the cost-effectiveness analysis – and to provide an indication of the probability that the technology is likely to represent value for money.

24. We believe there is an opportunity to ensure closer liaison between health Economics and Procurement, to ensure the Welsh NHS is getting the best value for money.

Engagement with those involved in the development and manufacture of new medical technologies

25. We also believe there is a clear role for industry and innovators to be engaged in this process, especially with regards to understanding how the Welsh NHS makes decisions and procures medical technology.

26. There are a number of areas which would benefit from this including clarifying the appropriate point of entry into the Welsh NHS for suppliers depending on their development status (developing the technology, or requiring clinical data for regulatory approval). If we can provide an opportunity to at least address the "route" alongside the need for innovation then this would be a major step forward.

27. Welsh industry also has a clear appetite for participating in the strategic direction of the Welsh NHS, as well as a requirement to understand the direction of travel so that they can focus their own resources appropriately.

28. There are a number of groupings who should be involved in this process, including NHS clinicians, procurement, academia, trade bodies, and other interested organisations such as MediWales.

The Need for joined up approach to commissioning

29. One of the problems with stimulation a dialogue related to new technology adoption is how to persuade Clinicians , Health Boards and Trusts **not** to leap on every new technology and to have confidence in the

system. A successful strategy as outlined in this paper will open up the opportunity for interested clinicians to engage in the process for the wider benefit of the Welsh NHS, as opposed to operating in a silo. This should enable us to get past the 'I need to make my own decisions' issue, by demonstrating that the assessment and selection process is balanced, fair, credible, and most importantly, clinically driven.

30. At a time when the overall NHS budget is under huge pressure it is also important to take a more flexible approach to budgets. We need to better consider the whole life costs and total clinical pathways and recognise that whilst the cost of a particular device may be more expensive, if you look at the total costs then this may have an overall benefit. We cannot have a system which prevents this approach because of "silo budget mentality".

31. Of course, there must be acknowledgement that many technologies and devices will be rejected when subjected to this level of scrutiny, and we should recognise that not every claim made by companies on potential clinical or financial advantage will stand up to detailed scrutiny. Nevertheless, even in these circumstances, this will provide invaluable feedback to industry, allowing them to redesign and develop a more successful device. Within the Welsh NHS we have a number of areas where this is already successful, delivering better and in many cases, more cost effective devices to Welsh clinicians and patients - Fluid warming, Compression hosiery, Tonsillectomy and Wound dressings.

32. By assessing evidence, laboratory studies, usability studies, health economics, and a number of other factors, a balanced view can be formed.

Process management

33. To achieve the ambitious aims outlined above, we believe that a group with strategical oversight is necessary, such as an All Wales Medical Device (or Technology) Management Group. This could provide a vehicle for a range of technical and clinical assessments in a similar way to that currently working within the drugs field. It should also coordinate and facilitate conversations between stakeholders, as no single person/organisation has the complete answer.

34. The system will also need an operational arm, and for that we believe Shared Services Partnership (Procurement) has a key role to play in this process and could provide a very useful "bridge" between industry and the needs of NHS Wales. Another area of critical importance is the potential impact of Procurement on the Welsh economy, and whether procurement could help grow and develop Welsh industry as part of this initiative, Welsh Government has already committed money to the Life Science section and Ministers are considering innovative approaches to products and the way this should or could work.

35. There also needs to be a body external to the NHS - who has the role of ensuring successful Welsh Health innovation can be developed worldwide, and can support companies in developing devices which have significant international potential.

36. An appropriate model for the strategic body is already in place - the AWMSG - which has been shown to be effective in the medicines arena. Perhaps more importantly, it also has authority and credibility, both of which are necessary to ensure engagement and compliance.

37. We strongly believe that medical devices are no less important than medicines in the modern Welsh NHS. At present, we are doing a dis-service to staff and patients through insufficient focus on the devices arena.

Joined up Working Works!

38. We have a number of Welsh examples where a joined up approach to Procurement that involves the correct level of clinical engagement can really work. The Tonsillectomy example referred to earlier is an excellent example where a process which coordinated a credible group of people involved who delivered a safe efficient outcome which wasn't subject to multiple hospitals running their own trials. Wales followed the SEAC guidance, took Ministerial advice on the direction of travel, and delivered an effective solution with measurable benefits for patient safety.

39. Other examples exist, some of which have required far more effort to gain acceptance. If offered the opportunity to provide verbal evidence then we can expand on these,

Summary

40. There are a number of strands which could be coordinated at a National level:

    I. Horizon scanning for new devices/technologies which may be of benefit (clinical advantage, clinical safety, or financial);

    II. Identification of areas of focus: based on clinical risk, clinical benefits and potential savings (whole of life costings – including direct costs or indirect costs, such as litigation settlements);

    III. Deciding which pre-procurement route is appropriate – laboratory, simulation (for example, human factors) or clinical assessments;

    IV. Deciding which post-procurement monitoring system is necessary – product sampling (lab testing), formal surveillance (as per single-use tonsillectomy & neuraxial non-luer devices), use of incidence data (NRLS, SMTL, MHRA);

    V. Publicising the work programme to give industry (especially Welsh industry where liaison should be easy to facilitate) the opportunity to propose and submit technologies, and participate in procurement exercises. We should open up and clarify the 'rules of engagement' for industry and medical devices.

    VI. This is not just about novel technology – it is also about procuring appropriate technology and devices which are fit for purpose, evidence based, and which are cost effective.

    VII. A 'joined up' approach to commissioning. The Best Practice and Innovation Board have noted Procurement's potential to drive technology adoption on a national scale, especially as it is the single point of entry to the Welsh NHS where Procurement can also act as the gatekeeper.

41. The benefits of the above include

    I. Better clinical outcomes;

    II. Better assessment of new technologies;

    III. Better clinical engagement and adoption – in particular addressing clinicians perception of medical device regulation and CE marking;

    IV. Better risk management - reduced cost pressure on Welsh Risk Pool/litigation, and mitigating the risks currently inherent in the medical device sector;

    V. Better value for money;

    VI. Better outcomes for the Welsh Economy - involvement and opportunities for the Welsh medical device sector;

We would be happy to provide oral evidence if invited.

Appendix I

This response has been developed and supported by the following:

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- Pete Phillips, Director, SMTL
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- Alun Tomkinson - ENT surgeon, C&VHB

- Simon Poulter - Anaesthetist ABMU HB, Chair of Medical Commodity Advisory Group)
- Gordon Staple - Paediatric anaesthetist ABMU HB, ACD Anaesthetics ABHU HB)
- Mark Stacey - Obstetric anaesthetist, C&V HB
- Prof. Harold Thimbleby - Human Factors, Swansea University.