Response to NHS Chief Executive’s Open Call for Evidence and Ideas

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Amgen Response to the NHS Chief Executive Innovation Review: Call for Evidence and Ideas

Amgen is committed to discovering, developing and delivering innovative medicines to fight serious illness. A biotechnology pioneer since 1980, Amgen pioneers the development of novel products based on advances in recombinant DNA and molecular biology, and launched the biotechnology industry’s first blockbuster medicines.

Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. Today as the world’s biggest biotechnology company serving millions of patients, Amgen continues to be an entrepreneurial, science-driven enterprise dedicated to helping people fight grievous illness.

This is the formal response from Amgen to the Innovation Review; the submission outlines suggested changes to the current NHS that would support; 1) delivery of improved patient outcomes through innovation to care pathways and 2) overcome the barriers to innovation that exist in the current system. The potential solutions are outlined in section 4.0.

1.0 Remain focused on improving patient outcomes

Amgen welcomes the move to an outcomes focused NHS, with a commitment to putting “patients at the heart of everything we do” in order to deliver healthcare amongst the best in the world\(^1\). We need to ensure that people at all levels within the NHS are focused on what’s important, that the decisions made and the action taken drive better outcomes for patients. A single minded focus on improving patient outcomes will create a health service that encourages not stifles innovation.

The levers and incentives within the system at national, regional and local level must ensure measurement of outcomes is truly integrated within the NHS. We must identify and remove existing barriers to achieving this goal.

Under the current system the value of healthcare innovation in driving better outcomes is not fully recognised. We should ensure that outcome measures are sufficiently broad to appropriately recognise and reward the true benefits of innovation and to encourage future innovation for example; value to society and a comprehensive assessment on quality of life of the patient

2.0 Innovation in care pathways and service re-design

Innovation in how healthcare is delivered will be critical to achieving both better patient outcomes but also to delivering the £20bn efficiency savings required in the current environment. Amgen believes that innovative medicines can be a big part of the solution to rising healthcare costs, not the source of the problem. This requires the Pharmaceutical industry and NHS to work together more effectively than we have in the past, to identify how to unlock the real value that medicines can bring both to patients and the healthcare system.
In the current UK environment one of the greatest opportunities to add value exists through using medicines to support re-design of existing care pathways. Moving unnecessary care out of the hospital setting is one example of how we can work together to deliver meaningful innovation within the NHS.

2.1 Supporting community delivery of cancer services

Community delivery of cancer services is identified in Building Britain’s Future and NHS 2010-2015 from good to great as an area where high impact changes can be made, the current cancer strategy confirms the direction of travel encouraging more services closer to home².³.

The key drivers are improved patient choice and experience, as well as managing the ongoing increasing demand for chemotherapy. There is also significant potential to deliver efficiencies within the current system.

Medicines that facilitate the movement of care out of the hospital have a vital role to play. There are many innovative models for how cancer care can be provided closer to patients’ homes. Amgen are currently working with a number of forward thinking local NHS organisations to pilot how two treatments, can support their ambitions to change the current model of care.

Amgen case studies

There are currently two pilots in the early stages of development to identify how XGEVA® (denosumab), an innovative new treatment for the prevention of bone metastases in advanced cancer patients, can support delivery against local goals.

In three large, identically designed, multicentre, randomized, double-blind, phase III clinical trials denosumab demonstrated a superior, statistically significant, clinically meaningful, consistent and robust treatment effect on the reduction of SREs compared with zoledronic acid. These studies provide the largest and most robust evidence package constructed to date in SRE prevention in patients with bone metastases, involving a total of 5,554 patients with solid tumours (breast cancer n=2,046; prostate cancer n=1,901; other solid tumours n=1,597).

Advice from NHS stakeholders helped identify that the route of administration for XGEVA® offers significant additional value to the NHS. The subcutaneous method of administration presents clear advantages over existing IV bisphosphonate therapy allowing the provision of care in the community, freeing capacity in hospital, releasing cash and delivering a better outcome for the patient both in terms of efficacy and patient experience. Early estimates from one leading cancer center suggest this could result in better outcomes for patients, and deliver up to £500,000 of efficiency savings for the PCT cluster (South London) that the cancer centre serves.

Amgen is also working with the Clatterbridge Centre for Oncology to pilot ways in which we can move the provision of Neulasta (pegfilgrastim) Granulocyte - Colony Stimulating Factor (G-CSF) out of the hospital setting for appropriate patients.

We aim to submit a case study sharing the results and learning’s from the XGEVA® pilot later in 2011.
2.2 Redesigning the care pathway in osteoporosis

Osteoporosis affects over two million women in the UK\(^5\); every year 300,000 people suffer a fragility fracture\(^6\) including 76,000 hip fractures\(^7\). This presents a considerable burden to the health economy and impacts patient outcomes. In the UK, 1,150 people die every month following a hip fracture\(^8\).

Historically the treatments available have also presented challenges, it is estimated that 25% of patients are not suitable for bisphosphonates, and that 68% of patients on oral bisphosphonates have stopped taking their treatment within one year\(^9\). The IV bisphosphonates require patients to travel to hospital for treatment taking up valuable IV chair capacity and nurse resource.

Prolia® (denosumab) uniquely protects throughout the skeleton increasing bone mass at both cortical and trabecular bone, resulting in fracture risk reduction at all key osteoporotic sites and with 90% compliance vs. an oral weekly treatment.

Prolia is administered in the form of a subcutaneous injection, which can be conveniently given on a six-monthly basis making it suitable for administration in primary care. NICE guidance gained in October 2010 supported delivery of the medication in this setting\(^10\).

This sort of innovative approach requires joint working from the NHS and industry, but also the ability to look beyond some of the barriers that currently exist in the NHS. Encouraging and incentivizing such innovative approaches can deliver better outcomes for patients and efficiency savings for the total health economy.

3.0 Barriers to delivering innovation to the patient pathway

As recognised within the healthcare and life sciences growth review the NHS has an excellent track record for delivering innovation but the spread can be slow, with sometimes even the best innovation failing to achieve widespread use\(^4\). Amgen believe addressing the barriers outlined below would allow the NHS to deliver the innovation in patient pathways required to achieve better outcomes.

3.1 Silo budget mentality

There is evidence within the local NHS (Hospital Trusts and PCTs) of a move towards focusing on the silo drug budget as a solution to managing the short term cost constraints. This is especially evident when people are measured on bringing the drug budget down with no accountability for the impact on the wider health economy or outcomes for patients.

Silo budgeting discourages an integrated patient pathway approach, thereby limiting opportunities for improvement to patient outcomes. In some cases, silo budgeting can even result in deterioration to existing outcomes. It also often fails to deliver the intended savings as costs are transferred from one budget to another.

Amgen case study – Silo budget focus within the management of febrile neutropenia (FN)

Chemotherapy induced neutropenia (FN), is recognised as one of the most serious complications of cancer treatment\(^11\). FN may result in significant consequences for patients including; mortality, intensive care admission and medical complications. The National Confidential Enquiry into Patient Outcomes (NCEPOD) highlighted the high number of avoidable deaths from FN\(^11\).

In the UK the management of FN has a substantial economic burden, with the cost per FN episode in breast cancer estimated at £3,000 to £4,300 \(^{12,13}\). Episodes of FN will predominantly present in
the community; neutropenic sepsis is a medical emergency and usually presents through A&E leading to increased hospital admissions.

There are two types of G-CSF available to prevent FN Neulasta (pegfilgrastim) & daily G-CSF (including biosimilars). Many trust guidelines recommend Neulasta over daily G-CSF due to a number of benefits to the patient and local NHS. Neulasta requires only 1 injection per chemotherapy cycle versus 6-14 for daily G-CSF reducing the capacity required from district nurses to deliver the treatment. Neulasta also delivers a greater reduction in the risk of FN 7% Vs 18% when dosed as according to clinical practice resulting in fewer avoidable emergency admissions and potential deaths.

A silo drug budget mentality in some local areas is leading to procurement driven switches away from Neulasta to daily G-CSF because the acquisition costs of daily-G are lower than pegfilgrastim. This is happening against the recommendation of clinicians who are concerned about the impact on patient outcomes. In some areas there is even an acceptance of the negative impact this will have on the health system elsewhere by potentially increasing emergency admissions and reducing district nurse capacity. Unfortunately, the decision to switch is based on the priority to reduce the drugs budget and does not consider the wider impact on the local NHS. One leading cancer centre switched to daily G-CSF in 2010 and has subsequently moved back to Neulasta following a negative impact to both patient outcomes and the increased pressure on the local NHS (emergency admissions & bed days).

Please see appendix A for budget impact analysis

3.2 Multi layered assessments of new products beyond NICE

Within the current system there are multiple layers of assessment that take place even after positive NICE guidance (PCT, Trust formularies and Regional Technology Appraisal Groups). This leads to inefficiencies, duplication and complexity in local decision making which slows the integration of innovative new drugs within the care pathway. As a result the NHS does not receive the outcome or efficiency savings identified through the NICE appraisal process; it also leads to unwarranted variation in delivery of care.

Amgen/GSK case study – barriers to adoption of NICE approved medicines

On 27th October, NICE approved Prolia (denosumab) for use in osteoporosis patients who are not suitable for bisphosphonates. Guidance was for initiation of the product in secondary care with subsequent delivery to occur almost exclusively in primary care.

Despite clinical demand there has been slow uptake of Prolia, currently only 25% of PCTs have included Prolia in their local formularies. Furthermore in 34% of PCTs, the medication is restricted to administration in secondary care only. This ignores the opinion of the clinical experts and NICE’s appraisal committee regarding anticipated setting of administration. It also means the possible benefits of service re-design and efficiency savings are not being realised. The slow uptake is likely driven by the current constraints on local NHS budgets which lead to multiple layers of assessment. Often this can mean although the treatment is considered cost effective it may also be considered unaffordable to the local NHS.

The solutions below outline our initial thinking but we would be keen to work with you to develop this further.
4.0 Ensure everyone at every level is measured on improving patient outcomes

People need to be held accountable for the wider implications of decisions around healthcare and medications to ensure that costs are not just transferred from one budget to another within the system. Holding people to account for patient outcomes will focus everyone on what’s most important. In some cases, choosing a medication with a higher acquisition price may deliver better outcomes to the patient and result in efficiency savings to the wider healthcare system.

To make this happen we would recommend the following changes to existing NHS levers:

**CQUIN** – The current budget for CQUIN is uplifted significantly, with payments delivered to NHS organisations for achievement against the five domains outlined in The NHS Outcomes framework. We would also recommend the inclusion of a specific payment for delivery of innovation in the care pathway to move unnecessary care out of the hospital setting. This payment would require evidence of an integrated approach across primary and secondary care.

**QOF and COF** – We would recommend that both frameworks include a significant number of points that can be gained from delivery against the NICE Quality standards. In addition clinical commissioning groups and individual practices should be able to gain payments for delivering integrated service re-design against one of the agreed national priority areas for example cancer.

Expanding The Right Care Atlas of Variation would also be valuable tool to help increase the transparency of outcomes at local NHS level. This would be an important resource to help evaluate local performance against the five domains of the NHS Outcomes Framework. An example of additional metrics for inclusion would be to further breakdown the hospital admissions currently measured to examine the route cause, including FN admissions would help to understand the progress being made against the NCEPOD report.

**Analysis of medications and the outcomes delivered** should be broadened to take into account societal benefits. The government has already indicated societal benefits will be a component of value based pricing from 2014. In addition, the current direction of travel for NICE to consider sensitivity analysis that does not discount humanistic (non-monetary) benefits could be expanded beyond the recent addendum to the methods guide to use a lower discount rate for QALYs in long term conditions for young people. We welcome the expansion of the role of NICE to include evaluations of diagnostics this will be critical to help encourage reform throughout the care pathway. This could be further strengthened if NICE were to undertake a program of activities for disinvestment.

4.2 Automatic inclusion on formulary for NICE-approved medicines

Automatic inclusion of NICE-approved medicines on local formulary’s without the need for reassessment, empowering clinicians to freely prescribe innovative medicines approved by NICE for eligible patients.

Such a solution would remove the need for multiple structural layers of assessment within the NHS; bodies such as the regional technology appraisal groups would no longer be required and could potentially be removed from the system releasing valuable savings. To make this happen in the first instance there may need to be an additional incentive payment through CQUIN or COF for inclusion of NICE approved medicines locally.
4.3 Strengthen the role of NICE in the implementation of their guidance

The NHS constitution enshrines the right to NICE approved medicines with mandatory funding within the NHS. However in the current cost-constrained environment that alone is not enough, local NHS organisations are making decisions that medicines may be cost effective but are not affordable.

It would be worth considering a strengthened role for NICE regarding implementation of their guidance; this would help achieve consistent and rapid implementation of NICE guidance across the NHS. To help address the challenge of innovation within the care pathway the current “implementation template” would need to be further developed. This could include; recommendations of pathway redesign to optimise end-to-end funding and identify areas for in-pathway disinvestment (where appropriate).

Use of the current levers within the system would be beneficial to help achieve the behavioral change required. This could be in the form of a CQUIN and/or QOF payment specifically for the implementation of NICE guidance. NICE in collaboration with the NHS commissioning board would need to undertake evaluation of performance against this measure.

4.4 Identify priority areas to trial agreed solutions

Tackling the uptake and spread of innovation in an organisation as large and complex as the NHS will always be difficult, but to achieve this across the entire NHS will be a real challenge. One option would be to start implementation of the agreed solutions in a small number of high impact areas. Cancer would be a good option due to the strong clinical leadership, the existence of the Improving Outcomes a Strategy for Cancer and a history of implementing new processes.

This type of pathfinder approach will allow refinement of the solutions but also allow the NHS to see the benefits of the planned changes.
References

1. The NHS outcomes framework


3. Improving Outcomes a Strategy for Cancer: January 2011

4. The Plan for Growth

5. NICE technology appraisal guidance 161

6. BOA-BGS 2007 Blue Book


8. Osteoporosis facts & figures, Dr Foster Health. Downloaded from:
   http://www.drfosterhealth.co.uk/medical-dictionary/conditions/osteoporosis/facts-and-figures.aspx

9. Li L et al. OP54 Non-persistence to anti-osteoporosis medications in the UK using the general practice research database (GPRD). *Rheumatology* 2010; 49: Supplement 1

10. NICE technology appraisal TA 204. Issued Oct 2010
    http://guidance.nice.org.uk/TA204

11. For better, or Worse? A review of the care of patients who died within 30 days of receiving systemic anti-cancer therapy NCEPOD
    http://www.ncepod.org.uk/2008sact.htm EORTC


17. NHS Right Care Atlas of Variation
    http://www.rightcare.nhs.uk/

18. The NHS Outcomes Framework
## Appendix A

### Impact on the local NHS of switching from Neulasta (pegfilgrastim) back to daily G-CSF*

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Impact of switch</th>
</tr>
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<tbody>
<tr>
<td>Patients suffering from FN</td>
<td>11 additional patients with FN, adding £37,202 in treatments costs</td>
</tr>
<tr>
<td>FN deaths</td>
<td>A potential increase of 0.44 in FN deaths</td>
</tr>
<tr>
<td>% of patients receiving optimal chemotherapy</td>
<td>15% less patients receive optimal chemotherapy</td>
</tr>
<tr>
<td>In patient acute bed days</td>
<td>55 additional bed days</td>
</tr>
<tr>
<td>District nurse capacity</td>
<td>A capacity increase of 77 community nurse days, costing an additional £51,012</td>
</tr>
<tr>
<td>Drug acquisition cost</td>
<td>A reduction in cost of £34,000</td>
</tr>
<tr>
<td>Overall cost to local NHS</td>
<td>Increased cost of £53,596</td>
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</table>

*switch driven by silo drug budget focus

### Assumptions
- Modelled on 100 patients
- Daily G-CSF dosed for 7 days and dosed by weight
- Pegfilgrastim price £300
- Daily G-CSF = £20 (300mcg syringe) £32 (480mcg syringe)
- Cost per community nurse hour £76
- 80% of daily G-CSF administration in the community, 20% self administer
- FN rate for Neulasta 7%, for daily G-CSG 18%