Institution: London School of Economics and Political Science

Unit of Assessment: 10 - Mathematical Sciences

Title of case study: Improved monitoring of the NHS drugs bill

Period when the underpinning research was undertaken: 2011-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Chris Skinner	Professor of Statistics	2011-2020 (deceased)
Yajing Zhu	PhD candidate, Department of Statistics	2015-2018

Period when the claimed impact occurred: 2014-2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact (indicative maximum 100 words)

Research by Professor Chris Skinner on design and estimation methods for cross-classified sampling has led to reductions in sampling error for a UK Department of Health and Social Care survey of medicines pricing. The results of this survey are used to determine how much community pharmacies in England are reimbursed for medicines dispensed via NHS prescriptions. The reduction in sampling error resulting from Skinner's work has helped to ensure that reimbursement price adjustments are smoother and based on more accurate evidence. In turn, this helps ensure both efficiency in NHS spending on prescription medicines and a more stable and predictable NHS funding stream for community pharmacies. Ultimately, the research has contributed to increasing NHS finance in areas supporting improved health and individual wellbeing.

2. Underpinning research (indicative maximum 500 words)

Since joining LSE in 2011, and until his death in March 2020, Professor Chris Skinner led a continuing programme of research into the statistical methodology of sample surveys and censuses. This started with a 2011-2013 project on "Enhancing the use of information on survey data quality", supported by an ESRC Professorial Fellowship. Skinner's research was stimulated particularly by interactions with organisations conducting surveys and censuses. These included the Office for National Statistics (ONS), for whom he led an independent review of the methodology underlying future options for the census **[1]**, and the European Social Survey team at City University, with whom he collaborated to address methodological challenges arising in this survey on two further ESRC grants in 2013-2016.

The research underpinning impacts described here was stimulated by interaction with the UK Department of Health and Social Care (DHSC) about methods for monitoring NHS expenditure on medicines prescribed by general practitioners (GPs). This expenditure amounts to around GBP9 billion a year. Spending is governed by the Community Pharmacy Contractual Framework (CPCF), which was established in 2005 and renewed in 2019 for the period 2019-2024. Under the CPCF, pharmacies purchase medicines directly from the market; this determines the prices they pay for those medicines. Meanwhile, the DHSC sets the so-called "Drug Tariff" - the amount that pharmacies will be reimbursed for the cost of each medicine dispensed for an NHS prescription.

These arrangements allow pharmacies to retain a "medicines margin", that is, the difference between the prices at which pharmacies purchase medicines and the amount they are reimbursed by the DHSC. The medicine margin is intended to incentivise pharmacies to purchase cost-effectively for the NHS by rewarding them for purchasing medicines at or below the reimbursement prices set in the Drug Tariff. The current CPCF sets an overall target of GBP800 million per annum for the medicines margin. In other words, community pharmacies in England should be able to make GBP800 million each year by purchasing medicines cost-effectively for the NHS. If the margin is much more than this, the NHS will be out of pocket. If it is much less, community pharmacies may not be being fairly reimbursed or properly incentivised to make cost-effective purchases. The DHSC monitors whether this margin is achieved through a Margin Survey of pharmacy invoices and adjusts the reimbursement as necessary. This involves increasing or

decreasing the reimbursement prices of some medicines in the Drug Tariff in the following year to recoup any overspends or reimburse any underspends related to the margin from previous years.

The National Audit Office (NAO) reviewed the operation of the CPCF from its institution in 2005 to 2009 and found that the target for the medicines margin was exceeded by, on average, GBP277 million per annum (see Section 5, **[B]**). It concluded that "*uncertainty surrounding the actual level of the margin … should, in our view, have made getting a robust assessment of actual levels of margin more of a priority*". It further recommended that the DHSC "*be more timely in making adjustments to reimbursement prices … to manage the level of retained margin*" and "*continue to work with recognised experts in survey design and analysis to maintain and improve the invoice survey*".

Further to these recommendations, the DHSC invited Skinner to work with them on improvements to the methodology of the Margin Survey. To that end, they provided him with funding support for the periods 2013-2015 and 2018-2020. Skinner accepted their invitation because the Margin Survey presented novel statistical challenges for accuracy assessment and sampling design. These challenges related especially to its complex sampling scheme, in which a sample of medicines is crossed with a sample of pharmacies in the context of strong temporal effects associated with a volatile wholesale market for generic medicines.

The DHSC had already established basic design and estimation methods for the survey, working under the advice of Dr Pedro Silva (a former PhD student of Skinner, now in Brazil). However, they were concerned about the accuracy of estimates of the margin and sought further advice on how to improve this. Skinner subsequently developed a new approach to accuracy (standard error) estimation for such a "cross-classified" design (published in **[2]**). Unlike the earlier approach, this enabled the separate and interacting effects of medicine sampling and pharmacy sampling to be identified. In turn, this allowed the medicine and pharmacy sample sizes to be adjusted separately and in an efficient way to achieve the desired accuracy improvements. Skinner also extended his approach to capture the temporal aspect of the sampling, demonstrating the gain in accuracy which could be achieved by a shorter "rotation period" for the medicine sampling.

A further challenge addressed in **[2]** was the influence of outlying observations on accuracy. Skinner developed standard, error-based rules for identifying "influential observations" and a more sophisticated framework for Winsorization of such observations to reduce their influence on mean and standard error estimators. The key outputs of the research relevant to the impacts outlined here are closed-form analytic expressions for point estimators and standard error estimators, which are approximately unbiased under the complex sampling schemes.

Skinner started this research in April 2013. He was solely responsible for the key theoretical research, which was submitted in May 2015 and published later that year **[2]**. A paper setting out the relevance of this research to a wider class of business surveys was presented at the International Conference on Establishment Surveys in Geneva in June 2016. The research advanced earlier survey sampling work on cross-classified sampling, and attracted significant international as well as national attention. In France, for example, Juillard et al. (2017, *J. Amer. Statist. Ass.)* extended some of the ideas in **[2]** and applied them to a French longitudinal survey on childhood.

From April 2013 to February 2016, the research was primarily about statistical theory, informed by analyses of the Margin Survey data undertaken by the DHSC. In March 2016, Yajing Zhu began her involvement in the research, taking responsibility for managing Margin Survey data supplied by the DHSC to LSE, and programming statistical methods. This enabled a study of the numerical properties of the methods. Data from 2013/14, 2014/15, and 2015/16 were supplied initially; these were updated with data from 2016/17 and 2017/18 in October 2018.

Key researchers: Chris Skinner, Professor of Statistics, October 2011 to February 2020 (deceased); Yajing Zhu, PhD student at LSE, January 2015 to October 2018 (now Data Scientist, Roche).

3. References to the research (indicative maximum of six references)

[1] Skinner, C. J., Hollis, J., and Murphy, M. (2013). *Beyond 2011: Independent review of methodology*. Report to Office for National Statistics, London. Available at:

https://www.ons.gov.uk/census/censustransformationprogramme/beyond2011censustransformationprogramme/independentreviewofmethodology

[2]* Skinner, C.J. (2015). Cross-classified sampling: some estimation theory. *Statistics and Probability Letters*, 104, pp. 163-168. DOI: 10.1016/j.spl.2015.06.001.

*The asterisked output best indicates the quality of the underpinning research. *Statistics and Probability Letters* is a high-quality internationally refereed journal.

4. Details of the impact (indicative maximum 750 words)

The Pharmaceutical Services Negotiating Committee (PSNC) promotes and supports the interests of NHS community pharmacies in England. The results of the Margin Survey have major financial implications for such pharmacies. Accordingly, the PSNC takes a keen interest in its methodology and the DHSC seeks to ensure agreement with the PSNC regarding any changes to this. Skinner met with DHSC and PSNC members roughly twice a year to share and discuss reports of the LSE research. These inputs guided both the agenda for the LSE research and the implementation in the Margin Survey of methods developed in that research.

Impacts on the methodology of the Margin Survey
The main impacts of the research on the methodology of the Margin Survey have been: (a) more reliable estimators of accuracy (standard errors); and (b) improved accuracy. More specifically:

i)   New estimators of standard errors were introduced in 2016. These include methods for sub-annual estimates as well as for annual estimates, addressing the National Audit Office (NAO) recommendation about providing more timely results.

ii) Research on how to make estimation more robust to outlying observations (in line with the NAO recommendations) led to new standard error-based rules for identifying "influential observations"; these were implemented in 2019. New Winsorization methods were also proposed and are currently under consideration.

iii) Research into the dependence of the standard error on stratum sample sizes for both the drug and pharmacy samples supported a decision to increase the sample sizes for branded and generic drugs. This decision reflected research evidence showing that a greater effect could be achieved on reducing the standard error of the margin estimator by increasing the drug sample than by increasing the pharmacy sample.

iv) Research into the dependence of the standard error on rotation of the drug sample led to the rotation period being shortened from six to three months in 2018/19. This led to an estimated reduction of about 15% in the standard error of the margin estimator.

Skinner's role in this was the provision of expert - and, crucially, impartial - advice to both the DHSC and the PSNC as they negotiated an agreement on the optimal margin size. The changes outlined here had resourcing implications for both parties, who used the research insights provided by Skinner to support their productive collaboration on improvements to the Margin Survey. As a Public Health Analyst at the DHSC explains:

"The Margin Survey allows the DHSC to adjust reimbursements to pharmacies as necessary to make sure that they remain properly incentivised and fairly reimbursed, while protecting the NHS from overspending on the reimbursement of particular medicines…We sought to improve the accuracy of the model wherever possible and [Skinner] was able to provide impartial advice to both the DHSC and the PSNC on ways to achieve this. Changes to the sample size and its frequency, supported by [Skinner's] research, helped improve the survey's accuracy and confidence in its results." **[A]**

Subsequent impacts on adjustments of reimbursement prices in the Drug Tariff
The changes in the Margin Survey methodology have, in turn, supported adjustments of the reimbursement prices in the Drug Tariff. These adjustments have been achieved because the new methods allow: (a) reduced deviations between actual and target margins; and (b) reduced variability in adjustments over time.

The scale of adjustments has significantly reduced from the NAO's estimated deviations of hundreds of millions of pounds per annum in 2005-2009 (for the scale of this previous deviation,

see **[B]**). Deviations between the actual and target margins reflect unpredictable market changes, as well as Margin Survey estimation error, and it is difficult to quantify the relative contributions of these two factors. However, based on consideration of the impacts on Margin Survey standard errors, the order of improved accuracy relative to the target margin, as well as of reductions in variation in adjustments, is in the tens of millions of GBP per annum.

Benefits to the NHS
In recent years the NHS has faced considerable cost pressures, including in relation to expenditure on medicines. By reducing errors in the Margin Survey estimation, Skinner's research has helped ensure that the NHS is better able to recoup overspends on prescription drugs, supporting significant savings by reducing these sorts of losses. It is able to make this contribution because the adjustment of reimbursement prices for medicines is made *only* when evidence can be provided that the target margin has been missed. If that cannot be proven, the Drug Tariff cannot be adjusted and it is impossible for any overspend to be recouped. Inaccuracies in the estimated margin can therefore lead to a situation in which the NHS is unable to recoup overspends, simply because it cannot prove that the target margin has been missed.

For illustration, if the true annual margin is GBP860 million, the estimated margin is GBP850 million, and the standard error is GBP30 million, an approximate 95% confidence interval is GBP790-910 million. It may then be concluded that there is no statistical evidence that the target of GBP800 million has *not* been met and so the Drug Tariff does not need changing to recoup overspend. However, with a standard error of GBP20 million and a confidence interval of GBP810-890 million, it may be decided that there is an overspend of around GBP50 million (= GBP800-850 million) to be recouped.

These sorts of savings are desirable, not primarily for their own sake, but because greater efficiency in the use of NHS resources increases the amount of healthcare that can be financed from a given total NHS budget.

Benefits to community pharmacies and primary care networks
Community pharmacies have also faced severe cash flow challenges, with smaller independent pharmacies being especially vulnerable to "income variation and unpredictability" (see, for example, **[D]**). In October 2018, the PSNC noted that pharmacy reimbursement prices:

"*will reduce by GBP10 million per month from November 2018 for the next five months (until March 2019). This is to repay excess margin earned by pharmacies in previous years, in particular 2015/16 for which the results of the Margin Survey show that there was a significant over-delivery of margin.*" **[E]**

Against this backdrop, the PSNC expressed to HM Government its "*deep concerns about the financial pressures facing community pharmacy contractors and the fact that they would increasingly be unable to reinvest, given pressures from rising staff costs and business rates*" **[E]**. The impact of such cost pressures can be a reduction of services or, ultimately, closure - there were 134 net closures of "bricks and mortar" pharmacies between November 2016 and April 2018 **[F]**. In the broader context of plans to cut their NHS funding by GBP170 million, the then-Health Minister Alistair Burt estimated in January 2016 that between 1,000 and 3,000 pharmacies could face closure (BBC, 27 January 2016).

The research has helped ensure that community pharmacies receive a more stable and predictable funding stream from dispensing medicines. This results from the use of research findings to ensure that reimbursement price adjustments are smoother and made with accurate evidence from the Margin Survey **[A]**. In July 2019, the PSNC, NHS England and NHS Improvement, and the DHSC agreed a five-year deal for community pharmacies, guaranteeing funding levels until 2023/24. The deal secures pharmacy funding and sets out a clear vision for the expansion of clinical service delivery over the next five years, in line with the NHS Long Term Plan. Part of the agreement includes a commitment to:

"*working on a range of reforms to reimbursement arrangements to deliver smoother cash flow and fairer distribution of medicines margin and better value for money for the NHS.*" (**[G]**, p. 5)

The LSE research contributes to this commitment.

Benefits to patients

In May 2018, the CEO of the PSNC expressed concern about the effects of cost pressures on community pharmacies. In addition to closures, he noted that cuts meant that:

> "*[r]ather than investing in developments that could improve patient care and allow them to offer more services, contractors are having to consider reducing staff, opening hours and unpaid services, such as home delivery.*" **[F]**

These sorts of changes all have potentially negative implications for patients, especially the vulnerable and those in areas of high deprivation where pharmacies have traditionally been able to help reduce health inequalities **[F]**. By helping to ensure that pharmacies have a more stable and predictable stream of income from prescription medicines, the ultimate impact of the research is therefore a contribution to increased NHS finance in areas supporting improved health and individual wellbeing.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[A] Supporting statement from Public Health Analyst, Department of Health and Social Care, 9 March 2021.

[B] National Audit Office (March 2010), "The Community Pharmacy Contractual Framework and the retained medicine margin".

[C] House of Commons Committee of Public Accounts, "Price increases for generic medications", Sixty-Second Report of Session 2017-19, 12 September 2018. See pp. 5-6.

[D] Pharmaceutical Services Negotiating Committee, "PSNC Briefing 018/14: The settlement negotiations and the negotiating process - background information for contractors", September 2014.

[E] Pharmaceutical Services Negotiating Committee, "CPCF funding arrangements 2018/19".

[F] "Government figures show drop in pharmacy numbers since funding cuts", *The Pharmaceutical Journal*, 31 May 2018.

[G] Department of Health and Social Care, "The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan", 22 July 2019.